Package leaflet: Information for the user

# Flixotide

## 50 micrograms Evohaler

fluticasone propionate

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:


1 What Flixotide is and what it is used for
2 What you need to know before you use Flixotide
3 How to use Flixotide
4 Possible side effects
5 How to store Flixotide
6 Contents of the pack and other information


## 1 What Flixotide is and what it is used for

Fluticasone propionate belongs to a group of medicines called corticosteroids (often just called steroids). A very small dose of steroid is needed when it is inhaled. This is because it is inhaled straight to your lungs.

Flixotide works by reducing swelling and irritation in the lungs. It has what is called an 'anti-inflammatory action'.

Flixotide helps to prevent asthma attacks in people who need regular treatment. This is why it is sometimes called a 'preventer'. It needs to be used regularly, every day.

Flixotide will not help treat sudden asthma attacks where you feel breathless.

- A different medicine is used for treating sudden attacks (called a 'reliever').
- If you have more than one medicine, be careful not to confuse them.

## 2 What you need to know before you use Flixotide

### Do not use:

- if you are allergic to fluticasone propionate or the other ingredients of this medicine (listed in section 6)

### Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Flixotide if:

- you have ever been treated for tuberculosis (TB)
- you are using Flixotide at the same time as taking steroid tablets. Also if you have just finished taking steroid tablets. In both cases, you should carry a steroid warning card until your doctor tells you not to carry one

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using Flixotide.

If you find your reliever medicine is not working as well as before, or you need to take more than usual, go and see your doctor.

If your breathing suddenly gets worse, this can be life-threatening so seek medical advice urgently.

Contact your doctor if you experience blurred vision or other visual disturbances.

### Other medicines and Flixotide

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go into hospital.

In particular tell your doctor or pharmacist if you are taking any of the following:

- a type of antiviral medicine known as a 'protease inhibitor' (such as ritonavir) or cobicistat containing products which may increase the effects of fluticasone propionate. Your doctor may wish to monitor you carefully if you are taking these medicines.
- medicines used to treat fungal infections (such as ketoconazole)

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Flixotide.

### Flixotide with food and drink

You can use Flixotide at any time of day, with or without food.

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

### Driving and using machines

Flixotide is not likely to affect you being able to drive or use any tools or machines.

## 3 How to use Flixotide

Flixotide comes in three different strengths. Your doctor will have decided which strength you need. Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

### Using this medicine

The medicine in Flixotide should be inhaled using a special kind of inhaler called an Evohaler.

- Make sure that you have one and can use it properly.
- Instructions on how to use the inhaler are given as a step-by-step guide.
- If you are over 16 years of age and are on higher doses (above 1,000 micrograms daily) you should take your medicine via the Volumatic large-volume spacer device to help reduce side-effects in the mouth and throat. Your doctor, nurse or pharmacist will be able to advise you about this.
- Some people find it difficult to release a puff of medicine just after they start to breathe in. The Volumatic spacer device helps to overcome this problem. Your doctor, nurse or pharmacist will be able to advise you about this.
- **It takes a few days for this medicine to work and it is very important that you use it regularly.**

### Adults and Children over 16 years of age

Mild asthma

- The usual starting dose is 100 micrograms twice a day.

Moderate to severe asthma

- The usual starting dose is 250 to 500 micrograms twice a day.
- The most taken should be 1000 micrograms twice a day.

### Children (4 to 16 years of age)

- The usual starting dose is 50 micrograms twice a day.
- The most taken should be 200 micrograms twice a day.

**Flixotide Evohaler 50 micrograms is not recommended for children below 4 years of age.**

It is recommended that children being treated with steroids, including Flixotide Evohaler have their height checked regularly by their doctor.

Your doctor may give you a Flixotide Evohaler of a higher strength if your dose is increased.

**If you are using high doses of an inhaled steroid for a long time you may sometimes need extra steroids for example during stressful circumstances such as a road traffic accident or before an operation. Your doctor may decide to give you extra steroid medicines during this time.**

**Patients who have been on high doses of steroids, including Flixotide Evohaler for a long time, must not stop taking their medicine suddenly without talking to their doctor. Suddenly stopping treatment can make you feel unwell and may cause symptoms such as vomiting, drowsiness, nausea, headache, tiredness, loss of appetite, low blood sugar level and fitting.**

### Instructions for use

Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the Flixotide Evohaler properly or as prescribed, may mean that the medicine will not help your asthma as it should.

The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.

### Testing your inhaler

1 When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.

2 To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release a puff into the air. If you have not used the inhaler for a week or more, release two puffs of medicine into the air.

### Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1 Stand or sit upright when using your inhaler.

2 Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.

3 Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.

4 Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.

5 Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.

6 Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.

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**8** If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.

**9** Afterwards, rinse your mouth with water and spit it out

**7** Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.

**10** After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practise the technique together. You may find the Volumatic spacer device with a face mask, or the Babyhaler device, useful if you have to give Flixotide Evohaler to a baby or a child under 5 – speak to your doctor if you think you might need one of these.

Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. Your doctor, nurse or pharmacist will be able to advise you.

### Cleaning your Evohaler

To stop your inhaler blocking, it is important to clean it at least once a week. To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the metal canister from the plastic casing at any time.
- Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.
- Replace the mouthpiece cover.

Do not put the metal canister in water.

### If you use more Flixotide than you should

If you use more than you should, **talk to your doctor as soon as possible**. It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

### If you forget to use Flixotide

- Take the next dose when it is due.
- Do not take a double dose to make up for the forgotten dose.

### If you stop using Flixotide

- **Do not stop treatment** even if you feel better unless told to do so by your doctor.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

## 4 Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away.** You may need urgent medical treatment.

- allergic reactions (may affect up to 1 in 100 people) – the signs include skin rashes, redness, itching or weals like nettle rash or hives
- severe allergic reactions (may affect up to 1 in 10,000 people) - the signs include swelling of your face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed and collapse
- your breathing or wheezing gets worse straight after using your inhaler

### Other side effects include:

**Very common** (may affect more than 1 in 10 people)

- thrush in the mouth and throat

**Common** (may affect up to 1 in 10 people)

- sore tongue or throat
- hoarseness of voice

Problems with your mouth and throat can be reduced by doing certain things straight after inhaling your dose. These are brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your doctor if you have these problems with your mouth or throat, but do not stop treatment unless you are told to.

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):

- Pneumonia and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increased sputum production, change in sputum colour, fever, chills, increased cough, increased breathing problems
- Bruising

**Rare** (may affect up to 1 in 1,000 people)

- thrush (candidiasis) in the oesophagus

**Very rare** (may affect up to 1 in 10,000 people)

- sleeping problems or feeling worried, over-excited and irritable. These effects are more likely to occur in children
- joint pains
- indigestion
- level of sugar (glucose) in your blood may be increased
- the way steroids are produced by your body may be affected when using Flixotide. This is more likely to happen if you use high doses for a long period of time (e.g. 400 micrograms daily in children). This can cause:
  - children and young people to grow more slowly
  - something called 'Cushing's syndrome'. This happens when you have too much steroid in your body and it can cause thinning of your bones and eye problems (such as cataracts and glaucoma which is high pressure in the eye)

  Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

**Not known**: frequency cannot be estimated from the available data:

- depression, feeling restless or nervous. These effects are more likely to occur in children
- nosebleeds
- blurred vision

### Talk to your doctor as soon as possible if:

- after 7 days of using Flixotide your shortness of breath or wheezing does not get better, or gets worse
- you or your child is on high doses of inhaled steroid and become unwell with vague symptoms such as tummy ache, sickness, diarrhoea, headache or drowsiness. This can happen during an infection such as a viral infection or stomach upset. It is important that your steroid is not stopped suddenly as this could make your asthma worse and could also cause problems with the body's hormones

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Flixotide

- Keep this medicine out of the sight and reach of children.
- Clean your inhaler on a weekly basis and if it becomes blocked as described under 'Cleaning'.
- Do not use this medicine after the expiry date, which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.
- Store below 30°C. Protect from frost and direct sunlight.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The metal canister is pressurised. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn even when apparently empty.
- Replace the mouthpiece cover firmly and snap it into position.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If you are told to stop taking this medicine, return the inhaler to your pharmacist to be destroyed.

## 6 Contents of the pack and other information

### What Flixotide contains

- The active substance is fluticasone propionate
- The other ingredient is HFA 134a.

### What Flixotide Evohaler looks like and contents of the pack

- Flixotide Evohaler comprises an aluminium alloy can sealed with a metering valve, actuator and dust cap.
- Each canister contains 120 doses of 50 micrograms of fluticasone propionate.

### Marketing Authorisation Holder:

Glaxo Wellcome UK Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS

### Manufacturer:

Glaxo Wellcome S.A.
Aranda de Duero
Burgos
Spain

### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

**Product name** **Flixotide 50 mcg Evohaler**
Reference numbers 10949/0324

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was last revised in May 2021.**



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Package Leaflet: Information for the User

# **Ventolin** Evohaler 100 micrograms

## salbutamol sulfate

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions about your illness or your medicine, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**


1 What Ventolin Evohaler is and what it is used for
2 What you need to know before you use Ventolin Evohaler
3 How to use Ventolin Evohaler
4 Possible side effects
5 How to store Ventolin Evohaler
6 Contents of the pack and other information


## 1 What Ventolin Evohaler is and what it is used for

Ventolin Evohaler contains a medicine called salbutamol. This belongs to a group of medicines called fast acting bronchodilators.
- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Ventolin Evohaler is used to treat breathing problems in people with asthma and similar conditions. This includes relieving and preventing asthma brought on by exercise or other "triggers". These are things, which bring on asthma symptoms in some people. Common triggers include house dust, pollen, cats, dogs and cigarette smoke.
Ventolin Evohaler contains a propellant called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Ventolin Evohaler. This will make no difference to how your medicine works.

## 2 What you need to know before you use Ventolin Evohaler

**Do not use Ventolin Evohaler if:**
- you are allergic to salbutamol sulfate or any of the other ingredients of this medicine (listed in section 6).
- you unexpectedly go into early labour (premature labour) or threatened abortion.

**Warnings and precautions**
Talk to your doctor, nurse or pharmacist before taking Ventolin Evohaler if:
- your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). Your doctor may start or increase a medicine to control your asthma such as an inhaled corticosteroid.
- you have high blood pressure.
- you have an overactive thyroid gland.
- you have a history of heart problems such as an irregular or fast heartbeat or angina.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.

**Other medicines and Ventolin Evohaler**
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital.
In particular tell your doctor, nurse or pharmacist if you are taking:
- medicines for an irregular or fast heartbeat.
- other medicines for your asthma.

**Ventolin Evohaler with food and drink**
You can take Ventolin Evohaler at any time of day, with or without food.

**Pregnancy, breast-feeding and fertility**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

**Driving and using machines**
Ventolin is not likely to affect you being able to drive or use any tools or machines.

## 3 How to use Ventolin Evohaler

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

**Adults and adolescents aged 12 years and over**
- to relieve asthma - One or two puffs.
- to prevent asthma - Two puffs 10-15 minutes before exercise or exposure to a "trigger".
- for regular treatment - Two puffs up to 4 times a day.
- the maximum dose is 8 puffs in a 24 hour period.

**Children under 12 years of age**
- to relieve asthma - One puff. Two puffs if required.
- to prevent asthma - One puff 10-15 minutes before exercise or exposure to a "trigger". Two puffs if required.
- for regular treatment - Two puffs up to 4 times a day.
- the maximum dose is 8 puffs in a 24 hour period.

**Instructions for use**
- To help identify that the inhaler is Ventolin, there is an embossed letter V on the plastic case.
- Ventolin Evohaler produces a fine mist, which you inhale through your mouth into your lungs. Your doctor, nurse or pharmacist should show you how to use your inhaler. If you are not sure ask your doctor, nurse or pharmacist.
- Each Evohaler canister provides 200 puffs.

Do not use your inhaler more often than the doctor told you to. Tell your doctor if your medicine does not seem to be working as well as usual, as your chest problem may be getting worse and you may need a different medicine.
Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

**Testing your inhaler**

1 When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.

2 To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release two puffs into the air. If you have not used the inhaler for 5 days or more, shake it well and release two puffs of medicine into the air.

**Using your inhaler**
It is important to start to breathe as slowly as possible just before using your inhaler.

1 Stand or sit upright when using your inhaler.

2 Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.

3 Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.

4 Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.

5 Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.

6 Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.

### Asthma Control Test

The Asthma Control Test is one way to quickly assess your asthma control, giving you a simple score out of 25. Your healthcare professional may ask you additional questions during a consultation.

**Are you in control of your asthma? Or is your asthma in control of you? Here's how to find out**

**Step 1:** Read each question below carefully, circle your score and write it in the box.

**Step 2:** Add up each of your five scores to get your total Asthma Control Test ™ score.

**Step 3:** Use the score guide to learn how well you are controlling your asthma.

| | | | | | | |
|---|---|---|---|---|---|---|
| Q1 | During the **past 4 weeks**, how often did your asthma prevent you from getting as much done at work, school or home? | All of the time 1 | Most of the time 2 | Some of the time 3 | A little of the time 4 | None of the time 5 | Score: |
| Q2 | During the **past 4 weeks**, how often have you had shortness of breath? | More than once a day 1 | Once a day 2 | 3-6 times a week 3 | 1-2 times a week 4 | Not at all 5 | Score: |
| Q3 | During the **past 4 weeks**, how often did your asthma symptoms (wheezing, coughing, chest tightness, shortness of breath) wake you up at night or earlier than usual in the morning? | 4 or more times a week 1 | 2-3 nights a week 2 | Once a week 3 | Once or twice 4 | Not at all 5 | Score: |

Turn over for Questions 4 and 5.

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**7** Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.

**8** If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.

**9** After use always replace the mouthpiece cover straight away to keep out dust.

Replace the cover by firmly pushing and clicking into position.
Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.
Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in.
Practise the technique together. You may find the Volumatic spacer device, with a face mask, or the Babyhaler device useful if you have to give Ventolin Evohaler to a baby or a child under 5 - speak to your doctor if you think you might need one of these.
Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece.
If this does not help, your doctor, nurse or pharmacist will be able to advise you.

**Cleaning your inhaler**
To stop your inhaler blocking, it is important to clean it at least once a week.
To clean your inhaler:
- Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
- Rinse the plastic casing thoroughly under warm running water.
- Dry the plastic casing thoroughly inside and out.
- Replace the metal canister into the plastic casing and put on mouthpiece cover. Do not put the metal canister in water.

**If you take more Ventolin Evohaler than you should**
If you take more than you should, talk to a doctor as soon as possible.
The following effects may happen:
- your heart beating faster than usual
- you feel shaky.
- hyperactivity

These effects usually wear off in a few hours.

**If you forget to take Ventolin Evohaler**
- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

**If you stop taking Ventolin Evohaler**
Do not stop taking Ventolin Evohaler without talking to your doctor.
If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

## 4 Possible side effects

**If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.**
Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:
**Allergic Reactions** (may affect up to 1 in 10,000 people)
If you have an allergic reaction, stop taking Ventolin Evohaler and see a doctor straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

**Talk to your doctor as soon as possible if:**
- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these may affect up to 1 in 10 people.

If any of these happen to you, talk to your doctor as soon as possible.
**Do not stop using this medicine unless told to do so.**
Tell your doctor if you have any of the following side effects which may also happen with this medicine:
**Common** (may affect up to 1 in 10 people)
- feeling shaky
- headache.

**Uncommon** (may affect up to 1 in 100 people)
- mouth and throat irritation
- muscle cramps.

**Rare** (may affect up to 1 in 1,000 people)
- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilatation).

**Very rare** (may affect up to 1 in 10,000 people)
- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.

**The following side effects can also happen but the frequency of these are not known:**
- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

**If you think this medicine is not working well enough for you**
If your medicine does not seem to be working as well as usual, talk to your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra doses of Ventolin Evohaler unless your doctor tells you to.

## 5 How to store Ventolin Evohaler

- Keep this medicine out of the sight and reach of children.
- Store below 30°C. Protect from frost and direct sunlight.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The metal canister is pressurised. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn the inhaler even when it is empty.
- Do not use this medicine after the expiry date, which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6 Contents of the pack and other information

**What Ventolin Evohaler contains**
- The active substance is salbutamol sulfate.
- The other ingredient is HFA 134a.

**What Ventolin Evohaler looks like and contents of the pack**
Ventolin Evohaler comprises an aluminium alloy can sealed with a metering valve, actuator and dust cap.
Each canister contains 200 doses of 100 micrograms of salbutamol (as salbutamol sulfate).

**Marketing Authorisation Holder**
Glaxo Wellcome UK Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS

**Manufacturer**
Glaxo Wellcome, S.A.
Aranda de Duero
Burgos
Spain

**Other formats:**
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only)
Please be ready to give the following information:

| | |
|---|---|
| **Product name** | **Ventolin Evohaler** |
| Reference number | 10949/0274 |

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was last revised in April 2021**



| | | | | | | |
|---|---|---|---|---|---|---|
| Q4 | During the **past 4 weeks**, how often have you used your reliever inhaler (usually blue)? | | | | | Score: |
| | 3 or more times a day 1 | 1-2 times a day 2 | 2-3 times a week 3 | Once a week or less 4 | Not at all 5 | |
| Q5 | How would you rate your **asthma control** during the **past 4 weeks**? | | | | | Score: |
| | Not controlled 1 | Poorly controlled 2 | Somewhat controlled 3 | Well controlled 4 | Completely controlled 5 | |



**Total Score**

## What does your score mean?

**Score: 25 - WELL DONE**
- Your asthma appears to have been UNDER CONTROL over the last 4 weeks.
- However, if you are experiencing any problems with your asthma, you should see your doctor, nurse or pharmacist.

**Score: 20 to 24 - ON TARGET**
- Your asthma appears to have been REASONABLY WELL CONTROLLED during the past 4 weeks.
- However, if you are experiencing symptoms your doctor, nurse or pharmacist may be able to help you.

**Score: less than 20 - OFF TARGET**
- Your asthma may NOT HAVE BEEN CONTROLLED during the past 4 weeks.
- Your doctor, nurse or pharmacist can recommend an asthma action plan to help improve your asthma control.

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**How should I give Montelukast 4 mg granules to my child?**
This medicine is for oral use.

- Do not open the sachet until ready to use.
- Montelukast granules can be given either:
  - directly in the mouth;
  - OR mixed with a spoonful of cold or room temperature soft food (for example, apple sauce, ice cream, carrots and rice).
- Mix all of the contents of the Montelukast granules into a spoonful of cold or room temperature soft food, taking care to see that the entire dose is mixed with the food.
- Be sure the child is given the entire spoonful of the granule/food mixture immediately (within 15 minutes). IMPORTANT: Never store any granule/food mixture for use at a later time.
- Montelukast granules are not intended to be dissolved in liquid. However, your child may take liquids after swallowing the Montelukast granules.
- Montelukast granules can be taken without regard to the timing of food intake.

**If your child takes more Montelukast granules than he/she should**
Contact your child's doctor immediately for advice.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

**If you forget to give Montelukast granules to your child**
Try to give Montelukast granules as prescribed. However, if your child misses a dose, just resume the usual schedule of one sachet once daily. Do not give a double dose to make up for a forgotten dose.

**If your child stops taking Montelukast granules**
Montelukast granules can treat your child's asthma only if he/she continues taking it. It is important for your child to continue taking Montelukast granules for as long as your doctor prescribes. It will help control your child's asthma.

If you have any further questions on the use of this medicine, ask your child's doctor or pharmacist.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies with montelukast 4 mg granules, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast were:
- diarrhoea
- hyperactivity
- asthma
- scaly and itchy skin
- rash

Additionally, the following side effects were reported in clinical studies with either montelukast 10 mg film-coated tablets or montelukast 5 mg or 4 mg chewable tablets:
- abdominal pain
- headache
- thirst

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a pill containing no medication).

**Serious side effects**
**Talk with your doctor immediately** if you notice any of the following side effects with your child, which may be serious, and for which your child may need urgent medical treatment.

Uncommon (may affect up to 1 in 100 people)
- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- seizure

Rare (may affect up to 1 in 1,000 people)
- increased bleeding tendency
- tremor
- palpitations

Very rare (may affect up to 1 in 10,000 people)
- combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) (see section 2)
- low blood platelet count
- behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

**Other side effects while the medicine has been on the market**

Very common (may affect more than 1 in 10 people)
- upper respiratory infection

Common (may affect up to 1 in 10 people)
- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Uncommon (may affect up to 1 in 100 people)
- behaviour and mood related changes dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness dizziness, drowsiness, pins and needles/numbness
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

Rare (may affect up to 1 in 1000 people)
- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare (may affect up to 1 in 10,000 people)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering
- tender red lumps under the skin most commonly on your shins (erythema nodosum)

**Reporting of side effects**
If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Montelukast granules

**Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date which is stated on the sachet after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6 Contents of the pack and other information

**What Montelukast granules contains**
- The active substance is montelukast. Each sachet of granules contains montelukast sodium which corresponds to 4 mg montelukast.
- The other ingredients are mannitol, hydroxypropyl cellulose, sodium laurilsulfate and magnesium stearate

**What Montelukast granules looks like and contents of the pack**
Montelukast 4 mg granules are white to off-white granules.
Cartons of 7, 20, 28, 30 and 98 sachets.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

**Manufacturer**

Teva Operations Poland Sp. z o.o.
ul. Mogilska 80, 31546 Kraków
Country: Poland

**This leaflet was last revised in September 2022**

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TEVA UK LIMITED

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Tell your doctor or pharmacist if any of the following side effects occur or worsen.

**Not known** (frequency cannot be estimated from the available data):
Usual side effects include: irregular heartbeat (including palpitations and rapid heartbeats), high blood pressure, sweating, nausea, vomiting, difficulty breathing, paleness, headache, hypertension, dizziness, weakness, tremor and apprehension, nervousness or anxiety.

**Rare** (may affect up to 1 in 1,000 people)
Cardiomyopathy has been seen in patients treated with adrenaline.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How To Store EpiPen®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not store above 25 °C. Do not refrigerate or freeze.

Keep container in the outer carton in order to protect from light. When exposed to air or light, adrenaline deteriorates rapidly and will become pink or brown.

**Please remember to check the contents of the glass cartridge in the EpiPen® Auto-injector from time to time to make sure the liquid is still clear and colourless. Do not use this medicine if you notice that the liquid is unclear, coloured or contains solid particles. Replace the Auto-injector by the expiry date or earlier if the solution is discoloured or contains a precipitate (solid particles).**
Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
See also section 3 – Directions for use.

## 6. Contents of the Pack and Other Information

**What EpiPen® contains**
The active substance is adrenaline 0.3 mg (300 microgram).

The other ingredients are: Sodium Chloride, Sodium Metabisulphite (E223), Hydrochloric Acid, Water for Injections.

**What EpiPen® looks like and contents of the pack**
Clear and colourless solution in a pre-filled pen (Auto-injector).
The Auto-injector (single-dose) contains 2 ml solution for injection. Each auto-injector delivers one single dose (0.3 ml) of adrenaline.
The exposed needle length is approximately 15 mm for EpiPen.

**Marketing Authorisation Holder and Manufacturer**

**Marketing authorisation holder:**
Mylan Products Ltd,
Station Close, Potters Bar, Hertfordshire,
EN6 1TL, UK

**Manufacturer:** MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg, Germany

**This leaflet was last revised in May 2021.**

If this leaflet is difficult to see or read and you would like it in a different format, please contact Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK

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Mylan





PATIENT INFORMATION LEAFLET

P090820012998

# EpiPen® Auto-Injector 0.3 mg Adrenaline

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**
1. What EpiPen® is and what it is used for
2. What you need to know before you use EpiPen®
3. How to use EpiPen®
4. Possible side effects
5. How to store EpiPen®
6. Contents of the pack and other information

## 1. What EpiPen® is and what it is used for

EpiPen® contains a sterile solution of adrenaline for emergency injection into the outer part of the thigh muscle (intramuscular injection).
EpiPen® is to be used for the emergency treatment of sudden life threatening allergic reactions (anaphylactic shock) to insect stings or bites, foods or drugs or exercise. The reaction is the result of the body trying to protect itself from the allergen (the foreign substance that causes the allergy) by releasing chemicals into the blood stream. Sometimes the cause of the allergic reaction is not known.

Symptoms that signal the onset of an anaphylactic shock occur within minutes of exposure to the allergen and include: itching of the skin; raised rash (like a nettle rash); flushing; swelling of the lips, throat, tongue, hands and feet; wheezing; hoarseness; shortness of breath; nausea; vomiting; stomach cramps and in some cases, loss of consciousness.
The medicine in the Auto-injector (the pen) is adrenaline which is an adrenergic drug.
It works directly on the cardiovascular (heart and circulation) system and respiratory (lung) system, to stop the possible fatal effects of anaphylactic shock by very quickly making the blood vessels smaller, relaxing muscles in the lungs to improve breathing, reducing swelling and stimulating heartbeat.

The EpiPen® is intended for immediate self administration by a person with a history or recognised risk of going into anaphylactic shock. If you are at risk, you should always keep your EpiPen® with you. It is designed as an emergency rescue therapy but you must get medical attention as soon as possible after its use.

## 2. What you need to know before you use EpiPen®

**Do not use EpiPen®**
There is no known reason why anyone should not use EpiPen® during an allergic emergency.

**Take special care with EpiPen®**
Adrenaline is essential for the treatment of anaphylaxis.
However, take special care with EpiPen®:
- particularly if you have heart disease as it may affect the medicines that you are taking and may bring on an attack of chest pain (angina)
- if you have an overactive thyroid
- if you have high blood pressure
- if you have diabetes
- if you are elderly, pregnant or the child weighs less than 25 kg (3 stone 13 lbs) as there is a greater risk of getting side effects.
- if you have increased pressure in your eye(s) (glaucoma)
- if you have severe kidney problems
- if you have a tumour in your prostrate
- if you have high calcium levels or a low potassium level in your blood
- if you have Parkinson's disease

Make sure you have discussed this with your doctor if any of these apply to you.

Patients with these conditions, or anyone who may be in the position to administer EpiPen® to a patient having an allergic reaction, should be properly instructed on how and when to give it.

**The instructions for use must be carefully followed in order to avoid accidental injection.**
EpiPen® should only be injected into the outer thigh.
It should not be injected into the buttock due to the risk of accidental injection into a vein.

**Warnings and precautions**
If you have asthma you may be at increased risk of severe allergic reaction. Anyone who has an episode of anaphylaxis should see their doctor about testing for substances they may be allergic to, so these can be strictly avoided in future.
It is important to be aware that an allergy to one substance can lead to allergies to a number of related substances. If you have food allergies it is important to check the ingredients in everything you ingest (including medicines) as even small amounts can cause severe reactions.
Accidental injection into the hands or fingers may result in reduced blood supply to these areas. If there is an accidental injection into these areas, you should go immediately to the nearest hospital casualty department for treatment.

If you have a thick-subcutaneous fat layer, there is a risk of the adrenaline not reaching the muscle tissue resulting in a suboptimal effect. In such individuals there may be a higher likelihood of needing a second injection with an additional EpiPen. Therefore you should ensure you carry two auto-injectors with you at all times.

In case of injection performed by a caregiver, immobilization of the patient's leg should be ensured during injection to minimize the risk of injection site laceration.

The needle should never be reinserted after use.

**Other medicines and EpiPen®**
When being prescribed EpiPen®, please tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines, including medicines obtained without a prescription as they may affect how the adrenaline works. This is especially important if you take any of the following:
Antidepressants such as tricyclic antidepressants or monoamine oxidase inhibitors (MAO inhibitors), since the effects of adrenaline may be increased.
Medicines that may make the heart sensitive to uneven beats (arrhythmias), such as digitalis, mercurial diuretics or quinidine.

- Medicines for the treatment of Parkinson's disease such as catechol-O-methyl transferase inhibitors (COMT inhibitors) and levodopa since the effect of adrenaline may be increased
- Beta-blocking medicines for heart disease or medicines to treat disorders of the nervous system as they can reduce the effect of adrenaline
- Medicines for thyroid disease
- Medicines that make you breathe more easily; used for asthma (theophylline)
- Medicines used in labour (oxytocin)
- Medicines used to treat allergies such as diphenhydramine or chlorpheniramine (antihistamines)
- Medicines that act on the nervous system (parasympatholytics).

Diabetic patients should carefully monitor their glucose levels after use of EpiPen® as adrenaline can reduce the amount of insulin made by the body, thus increasing the blood glucose level.

**Pregnancy**
Ask your doctor or pharmacist for advice before taking any medicine.
There is limited experience of the use of adrenaline during pregnancy. If you are pregnant, do not hesitate to use EpiPen® in an emergency, since you and your baby's lives may be in danger.
Discuss this with your doctor if you are pregnant.

**Driving and using machines**
The ability to drive and use machines is unlikely to be affected by the administration of an adrenaline injection but may be affected by an anaphylactic reaction. If affected do not drive.

**EpiPen® contains**
EpiPen® contains sodium metabisulphite (E223), which may rarely cause severe allergic reactions (hypersensitivity) or breathing difficulty (bronchospasm). However, you should still use the EpiPen® as there are no satisfactory alternatives.

This medicine contains less than 23 mg sodium per dose, i.e. essentially 'sodium-free'.

## 3. How to use EpiPen®

When your doctor prescribes EpiPen®, you must make sure you understand the reason it has been prescribed for you. You should be confident that you know exactly how and when to use it.
Always use EpiPen® exactly as your doctor or pharmacist has told you. If you are at all unsure about how to use it, ask to have the instructions repeated by your doctor, nurse or pharmacist.
It is recommended that your family members, carers or teachers are also instructed in the correct use of EpiPen.

If you have been stung by an insect, try to remove the stinger with your fingernails – do not squeeze, pinch or push it deeper into the skin.
If possible, put an ice pack on the area of the sting. Keep warm and avoid exercise.
For allergic reactions caused by foods make sure you remove any remaining food from the mouth immediately.

EpiPen® is intended to be used by people with a body weight above 25 kg (3 stone 13 lbs). For persons weighing less than 25 kg (3 stone 13 lbs), EpiPen® Jr. may be more appropriate for use.

**Dosage**
The dose will be decided by your doctor, who will adjust it individually for you. The usual adult dose for allergic emergencies is 0.3 mg adrenaline for injection into muscle (intramuscular use).
If you notice the signs of an acute allergic reaction, use EpiPen® immediately, through your clothing if necessary.

Each EpiPen® Auto-injector delivers one single dose of 0.3 ml liquid which is equal to 0.3 mg (300 micrograms) adrenaline. After use a volume of 1.7 ml will remain in the Auto-injector but this cannot be reused.

Sometimes a single dose of adrenaline may not be sufficient to completely reverse the effects of a serious allergic reaction. For this reason, your doctor is likely to prescribe more than one EpiPen® for you. If your symptoms have not improved or have deteriorated within 5-15 minutes after the first injection, either you or the person with you should give a second injection. For this reason you should carry more than one EpiPen® with you at all times.

**Method of administration**
The EpiPen® is designed to be used easily by people without medical training. EpiPen® should simply be jabbed firmly against the outer portion of the thigh from a distance of approximately 10 cm (4 inches). There is no need for precise placement in the outer portion of the thigh.
When you jab the EpiPen® firmly into your thigh, a spring activated plunger will be released, which pushes the hidden needle into the thigh muscle and administers a dose of adrenaline. If you are wearing clothes the EpiPen® can be injected through the clothes.

The instructions for use of the EpiPen® given below must be carefully followed.

EpiPen® should only be injected into the outer thigh.
**It should not be injected into the buttocks (your bottom).**

**Directions for use**
Before you ever need to use it, fully familiarise yourself with the EpiPen®, when and how it should be used (refer to diagram 1).

Follow these directions only when ready to use.

Hold the EpiPen® by the middle, never by the ends.
For proper administration, look at the diagrams and follow these steps:
– Never put thumb, fingers or hand over the orange tip.
– Do **not** remove blue safety cap until ready to use.


Diagram 1

1. Grasp EpiPen in dominant hand (the hand you use to write), with thumb nearest blue cap and form fist around unit (orange tip down)

2. With other hand pull off blue safety cap.



3. Hold the EpiPen at a distance of approximately 10 cm away from the outer thigh. The orange tip should point towards the outer thigh.

4. Jab the EpiPen firmly into outer thigh at a right angle (90 degree angle) (listen for click).
5. Hold firmly against thigh for 3 seconds. The injection is now complete and the window on the auto-injector is obscured.
6. EpiPen should be removed (the orange needle cover will extend to cover needle) and safely discarded.
7. Dial 999, ask for ambulance, and state anaphylaxis.

**As the EpiPen® is designed as emergency treatment only, you should always seek medical help immediately after using EpiPen®, by dialling 999, ask for ambulance and state 'anaphylaxis' even if symptoms appear to be improving. You will need to go to hospital for observation and further treatment as required. This is because the reaction may happen again at some time later.**
While waiting for the ambulance you should lie down with your feet raised unless this makes you breathless in which case you should sit up.
Ask someone to stay with you until the ambulance arrives in case you feel unwell again.
Unconscious patients should be placed on their side in the recovery position.
Make sure that you inform the healthcare professional that you have received an intramuscular injection of adrenaline or show them the container and/or leaflet.

A small air bubble may be present in the EpiPen® Auto-injector. It does not affect the way the product works.
Even though most of the liquid (about 90%) remains in the EpiPen® after use, it cannot be reused. However, you have received the correct dose of the medication if the orange needle tip is extended and the window is obscured.
After use, place the EpiPen® safely in the tube provided and bring it with you when you visit your doctor, hospital or pharmacy

**If you use more EpiPen® than you should**
In case of overdose or accidental injection of the adrenaline, you should always seek **immediate** medical help. Your blood pressure may rise sharply and it will need to be monitored. If you have any further questions on the use of this medicine; ask your doctor, pharmacist or nurse.

## 4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

Seek urgent medical advice immediately in case of accidental injection. Accidental injection of the pens in hands or fingers have been reported and may result in lack of blood supply to these areas.

Miss Gracie Mai Nomuoja
NHS Number: 7194033941
DoB: 04/07/2018
202 Fratton Road
Portsmouth
Hants
PO1 5HD

Island City Practice
Lake Road Health Centre
Nutfield Place
Portsmouth
Hants
PO1 4JT

Prescription Start Date: 16/03/2023
Prescription Expiry Date: 16/09/2023

R. J. BERRY Ltd.

**Patient Medication History**

[ ] Epimax excetra cream (Aspire Pharma Ltd), 500 gram, Apply frequently to moisturise dry skin, Additional Script Notes: Please note your Cetraben cream is now prescribed as Epimax Excetra cream. The active drugs remain identical., Last Issued: Thursday 16 Mar 2023, Next Issue Due: Thu 13 Apr 2023

[ ] Epimax ointment (Aspire Pharma Ltd), 500 gram, use as directed, Last Issued: Monday 29 Jun 2020, Issue from previous template, Reauthorised, Next Issue Due: Tue 30 Jun 2020

[ ] EpiPen Jr. 150micrograms/0.3ml (1 in 2,000) solution for injection auto-injectors (Viatris UK Healthcare Ltd), 2 pre-filled disposable injection, use as directed, Last Issued: Wednesday 27 Apr 2022, Issue from previous template, Reauthorised, Next Issue Due: Wed 25 May 2022

[ ] Flixotide 50micrograms/dose Evohaler (GlaxoSmithKline UK Ltd), 240 dose, inhale 2 doses twice daily, Last Issued: Thursday 16 Mar 2023, Next Issue Due: Thu 13 Apr 2023

[ ] Ventolin 100micrograms/dose Evohaler (GlaxoSmithKline UK Ltd), 400 dose, inhale 2-10 doses as needed/as per care plan, Last Issued: Thursday 16 Mar 2023, Next Issue Due: Sat 15 Apr 2023

**Patient Instructions**

PATIENTS – please read the notes overleaf

# Montelukast 4 mg granules
## For children from 6 months to 5 years of age

**Package leaflet: Information for the user**

**Read all of this leaflet carefully before you give this medicine because it contains important information.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


1. What Montelukast granules is and what it is used for
2. What you need to know before your child takes Montelukast granules
3. How to take Montelukast granules
4. Possible side effects
5. How to store Montelukast granules
6. Contents of the pack and other information


## 1 What Montelukast granules is and what it is used for

**What Montelukast granules is**
Montelukast granules is a leukotriene receptor antagonist that blocks substances called leukotrienes.

**How Montelukast granules work**
Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast granules improves asthma symptoms and help control asthma.

**When Montelukast granules should be used**
Your doctor has prescribed Montelukast granules to treat your child's asthma, preventing asthma symptoms during the day and night.
- Montelukast granules is used for the treatment of 6 months to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast granules may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- Montelukast granules also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Montelukast granules should be used depending on the symptoms and severity of your child's asthma.

**What is asthma?**
Asthma is a long-term disease.
Asthma includes:
- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of the airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

## 2 What you need to know before your child takes Montelukast granules

Tell your doctor about any medical problems or allergies your child has now or has had

**Do not give Montelukast granules to your child**
- if he/she is allergic to montelukast or any of the other ingredients of this medicine (listed in section 6)

**Warnings and precautions**
Talk to your doctor or pharmacist before you give Montelukast granules to your child
- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast granules is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.
- It is important that your child take all asthma medications prescribed by your doctor. Montelukast granules should not be used instead of other asthma medications your doctor has prescribed for your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- Your child should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/her asthma worse.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with montelukast (see section 4). If your child develops such symptoms while taking Montelukast granules, you should consult your child's doctor.

**Children and adolescents**
Do not give this medicine to children less than 6 months of age.

There are different form(s) of this medicine available for paediatric patients under 18 years of age based on age range.

**Other medicines and Montelukast granules**

Tell your doctor or pharmacist if your child is taking or has recently been given or might be given any other medicines, including those obtained without a prescription.

Some medicines may affect how Montelukast granules works, or Montelukast granules may affect how your child's other medicines work.

Tell your doctor if your child is taking the following medicines before starting Montelukast granules:
- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used to treat is hypertriglyceridaemia, mixed hyperlipidaemia and primary hypercholesterolaemia)

**Montelukast granules with food and drink**
Montelukast granules can be taken without regard to the timing of food intake.

**Pregnancy and breast-feeding**
This subsection is not applicable for Montelukast 4 mg granules since they are intended for use in children 6 months to 5 years of age.

**Driving and using machines**
This subsection is not applicable for Montelukast 4 mg granules since they are intended for use in children 6 months to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Montelukast is not expected to affect your ability to drive and use machines. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with montelukast may affect some patients' ability to drive or operate machinery.

**Montelukast 4 mg granules contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

## 3 How to take Montelukast granules

Always have your child take this medicine exactly as your doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.
- This medicine is to be given to a child under adult supervision. Your child should take Montelukast granules every evening.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

**For children 6 months to 5 years of age:**
The recommeded dose is one sachet of Montelukast 4 mg granules to be taken by mouth each evening.

If your child is taking Montelukast granules, be sure that your child does not take any other products that contain the same active ingredient, montelukast.

For children 6 months to 2 years old, Montelukast 4 mg granules are available.
For children 2 to 5 years old, Montelukast 4 mg chewable tablets and Montelukast 4 mg granules are available. The Montelukast 4 mg granules formulation is not recommended below 6 months of age.