

Package leaflet: Information for the patient

Fenorol 12 microgram inhalation powder, hard capsule
formoterol fumarate dihydrate

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 only for you. 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Fenorol is and what it is used for

Fenorol contains a medicine called formoterol. This belongs to a group of medicines called ‘long-acting beta-agonists’ or ‘bronchodilators’

It works by relaxing the muscles in your airways. This helps you to breathe more easily. It starts to work within 1 to 3 minutes and the effects last up to 12 hours.

Your doctor has prescribed this medicine to treat asthma or chronic obstructive pulmonary disease (COPD)

Fenorol is used in children 6 years and older, adolescents and adults.

Asthma

For asthma, your doctor will prescribe two asthma inhalers: Fenorol and a separate ‘corticosteroid’ inhaler. These should be used together.

- Fenorol is used to help prevent asthma symptoms from happening.
- Some people also use Fenorol when they require regular bronchodilator therapy.
- Fenorol can also be used before exercise to prevent asthma symptoms caused by exercise.

Chronic obstructive pulmonary disease (COPD)

Fenorol can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

2. What you need to know before you use Fenorol

Do not use Fenorol if

- you are allergic (hypersensitive) to formoterol or any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions

Talk to your doctor or pharmacist or nurse before using Fenorol.

Before you use Fenorol, tell your doctor or pharmacist if:

- You are diabetic. You may need some additional blood sugar tests while you are using Fenorol.
- You have high blood pressure or you have ever had a heart problem.
- You have heart rhythm disturbances or 'prolongation of the QT interval' (an abnormality visible on an electrocardiogram)
- You have problems with your thyroid gland.
- You have low levels of potassium in your blood. Your doctor may take blood samples to check the levels of potassium in your blood.
- You have severe liver problems such as liver cirrhosis.
- You have an aneurysm (dilation of an artery)
- You have pheochromocytoma (tumor in the adrenal gland which is a gland above the kidney that can affect your blood pressure).

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

Children and adolescents

Do not give this medicine to children below 6 years because there is insufficient data on safety and efficacy.

Other medicines and Fenorol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure and certain heart conditions), including eyedrops (such as timolol for glaucoma). This is because these medicines can decrease or inhibit the effect of Fenorol.
- Medicines for a fast or uneven heart beat (such as quinidine, disopyramide, procainamide).
- Medicines like digoxin, often used to treat heart failure.
- Diuretics, also known as 'water tablets' (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat asthma.
- Erythromycin (used to treat infections).
- Anti-histamines (such as terfenadine, astemizole or mizolastine).
- Other substances that dilates the airways (beta-2-agonists, bronchodilators, such as salbutamol).
- Ephedrine (used to treat asthma or as a decongestant).
- Tricyclic or MAO anti-depressants (such as amitriptyline).
- L-Dopa, used for Parkinson
- L-thyroxine, often used to replace Thyroid hormones
- oxytocin, often used to labor induction
- Alcohol

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

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work, as some anaesthetics (halogenated hydrocarbons) can cause heart rhythm disturbances.

The addition of anticholinergics (such as tiotropium or ipratropium bromide) to the treatment with Fenorol, can help to open your airways even more.

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 or pharmacist for advice before taking this medicine.
- If you get pregnant while using Fenorol, do not stop using Fenorol but talk to your doctor immediately.

Driving and using machines

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

Fenorol contains lactose

Fenorol contains lactose up to 25 mg per metered dose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk proteins. These may cause allergic reactions.

3. How to use Fenorol

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

Do not increase the dose of Fenorol prescribed by your doctor without talking to your doctor first.

If you are using Fenorol regularly for asthma or COPD you should continue to use your medicine, even if you have no symptoms.

Continue using the inhaler for as long as you have been told unless you have any problems. In that case, check with your doctor.

Fenorol must only be used with the inhaler provided. You must not try to inhale Fenorol capsules using another inhaler.

Do not put other types of capsules into the inhaler supplied with Fenorol.

Capsules are for inhalation only. Do not swallow the capsules.

The contents of the capsule must be inhaled using the inhaler provided.

Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using Fenorol, you should continue to use Fenorol but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- Your breathing is getting worse or you often wake up at night with asthma.
- You start getting chest tightness.
- You are not getting relief from your current dose.
- You need to take more than your usual dose for more than two days in a week.
- You need to use your Fenorol more often than usual before exercise.

These signs could mean that your asthma or COPD is not being properly controlled and you may need to be assessed for the doctor to establish different or additional treatment immediately.

Asthma

Fenorol should not be used in children under 6 years of age.

Adults (18 years and above)

- The usual dose is 1 inhalation, once or twice a day.
- Your doctor may increase this to 2 inhalations, once or twice a day.
- Some people also use Fenorol as a 'reliever inhaler'. If you get asthma symptoms, the usual dose is 1 inhalation when they happen.
- The daily dose for regular use should not exceed 4 inhalations. If required, an additional 1 to 2 capsules per day may be used for the relief of typical symptoms, provided the recommended daily maximum dose of 48 micrograms per day is not exceeded.
- Do not take more than 2 inhalations at any one time.

Children and adolescents (6 to 17 years)

- The usual dose is 1 inhalation once or twice a day.
- Some children also use Fenorol as a 'reliever inhaler'. If your child gets asthma symptoms, the usual dose is 1 inhalation when they happen.
- The daily dose should not exceed 2 inhalations.
- Your child should not have more than 1 inhalation at any one time. Children should only use this product under the supervision of an adult."

Your doctor (or asthma nurse) will help you to manage your asthma. Once your asthma is well controlled your doctor may consider it appropriate to gradually reduce the dose of Fenorol.

Asthma caused by exercise

If you or your child have asthma symptoms caused by exercise, your doctor may advise you or your child to use Fenorol before exercise as well. Fenorol should not be used in children under 6 years of age.

Adults (18 years and above)

- The usual dose is 1 inhalation before exercise.
- A total daily dose of more than 4 inhalations is not normally needed. This includes the inhalations that you take every day, when you get asthma symptoms and before exercise. Do not take more than 2 inhalations at any one time.

Children and adolescents (6 to 17 years)

- The usual dose is 1 inhalation before exercise.
- A total daily dose of more than 2 inhalations is not normally needed. This includes the inhalations that your child takes every day, when they get asthma symptoms and before exercise. Your child should not have more than 1 inhalation at any one time.

Chronic obstructive pulmonary disease (COPD)

- Only to be used by adults (aged 18 years and above).
- The usual dose is 1 inhalation once or twice a day.
- Your doctor may advise you to take extra doses for relief of your COPD symptoms.
- You should not have more than 4 inhalations a day.
- Do not take more than 2 inhalations at any one time.

How to use the capsules with the inhaler device

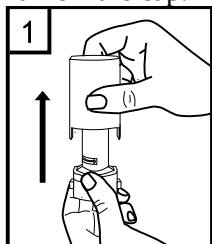
This medication is administered by inhalation. The contents of the capsules must be inhaled using the appropriate inhalation device reserved for this purpose (dispenser with a mouthpiece) and supplied in the box. **THE CAPSULES MUST NOT BE SWALLOWED.**

The effectiveness of this medication depends in part on the proper use of the inhalation device.

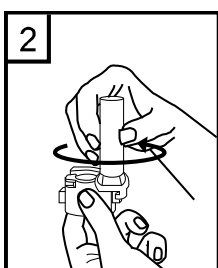
You should therefore read the instructions for use very carefully. If necessary, do not hesitate to ask your doctor or pharmacist for detailed explanations.

A child should be shown how to use the inhaler correctly and should only use it with the help of an adult.

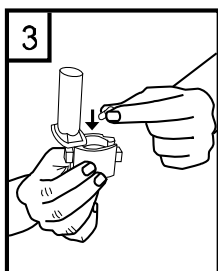
1. Pull off the cap.



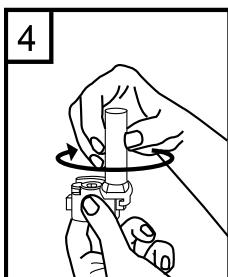
2. Hold the base of the inhaler firmly and turn the mouthpiece in the direction of the arrow to open.



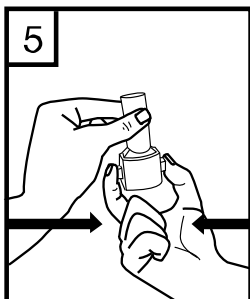
3. Take one capsule from the pack. Place it in the capsule-shaped compartment at the base of the inhaler. It is important that you only remove the capsule from the pack immediately before use.



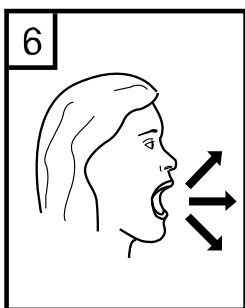
4. Twist the mouthpiece to the closed position until it clicks.



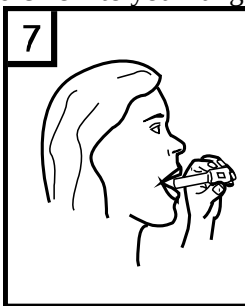
5. Keeping the inhaler upright, firmly squeeze the two buttons once only. This will pierce the capsule. Release the buttons. Although the capsule is now pierced, the powder will not be released until you inhale it.



6. Breathe out fully.



7. Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips around the mouthpiece and breathe in as quickly and as deeply as you can. As you breathe in, you will inhale the medicine into your lungs.



You should hear the capsule spinning in the inhaler. If you do not hear this whirring noise, the capsule may be stuck in the compartment. If this occurs, open the inhaler and loosen the capsule by prising it out of the compartment. Do not try to loosen the capsule by repeatedly pressing the buttons.

8. If you have heard the whirring noise, hold your breath for as long as you comfortably can while taking the inhaler out of your mouth. Then breathe normally. Open the inhaler to see if any powder is still in the capsule. If there is still powder in the capsule repeat steps 6 to 8.

9. After use, tip out the empty capsule and close the mouthpiece.

10. Replace the cap.

Cleaning your inhaler

If you need to clean the inhaler, wipe the mouthpiece and capsule compartment with a dry cloth or a clean soft brush

If you use more Fenorol than you should

If you use more Fenorol than you should, contact your doctor or pharmacist for advice immediately. The following effects may happen: trembling, headache or a rapid heart beat.

If you forget to use Fenorol

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

If you stop using Fenorol

Do not stop using Fenorol without talking to your doctor.

If you have any further questions on using your inhaler device, ask your doctor, or pharmacist or nurse.

4. Possible side effects

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

Serious side effects:

Stop taking Fenorol and contact a doctor or go to the nearest emergency department immediately, if you experience any of the following symptoms:

- An acute and rapidly worsening shortness of breath (paradoxical bronchospasm) with wheezing or coughing and difficulty breathing after inhaling your medicine (very rare, affects less than 1 in 10,000 people).
- Allergic reactions, e.g. if you feel close to fainting (due to low blood pressure), if you notice swelling of the hands and / or feet, swelling of the face, eyelids and lips (rare, affects less than 1 in 1,000 people).
- Symptoms of muscle weakness, muscle cramps, palpitations or abnormal heart rhythm (signs of low potassium levels in your blood; hypokalaemia) (rare, affects less than 1 in 1,000 people).
- Pains to the chest, jaw and back, brought on by physical effort and due to problems with the blood flow to the heart (signs of an angina pectoris) (very rare, affects less than 1 in 10,000 people).

Other side effects:

Common (affects less than 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use Fenorol.
- Headache.
- Tremors.

Rare (affects less than 1 in 1,000 people)

- Uneven heart beat.
- Nausea (feeling sick).
- Allergic reactions and excessive and prolonged contraction of the airway muscles causing breathing difficulty (bronchospasm)
- Feeling restless or nervous.
- Disturbed sleep.
- Fast heart beat.
- Involuntary muscle contractions.
- Muscle pain
- Anxiety
- Sore throat, dry mouth.

Very rare (affects less than 1 in 10,000 people)

- Certain heart rhythm abnormalities, prolongation of the QT interval (disorder seen during an examination of the heart through an electrocardiogram), swelling especially of the ankles and feet due to fluid retention (peripheral oedema).
- Hyperglycemia (increased sugar levels in the blood that can recognize a great thirst, frequent urination or fatigue).
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.
-
- Feeling dizzy

Not known (frequency cannot be estimated from the available data)

- Increase in blood levels of insulin, free fatty acids, glycerol and ketone bodies,
- Rash.

If you are sensitive to inhaling a dry powder, it may occasionally develop a throat irritation with coughing or hoarseness, this can be prevented by rinsing your mouth after inhalation.

If you experience muscle weakness, cramps, palpitations, or an abnormal heartbeat (including too fast), this may be a sign of too low potassium in your blood.

If you feel very thirsty, frequent urge to urinate, very tired, this may be due to too much sugar in the blood.

If you experience tightening pain in your chest (a sign of angina pectoris), see your doctor immediately. Hyperexcitability have been sporadically reported following inhalation of beta-2 agonists.. These effects were mainly observed in children up to 12years of age.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Fenorol

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

Blister pack: Do not store above 30 °C and store in the original package in order to protect from moisture.

Bottle pack: Store in the original package in order to protect from moisture.

Do not take the capsules out of the pack until you need them.

Do not use Fenorol after the expiry date which is stated on the carton, and bottle or blister after EXP. The expiry date refers to the last day of that month.

If your doctor tells you to stop using Fenorol, please take any unused capsules back to your pharmacist to be destroyed.

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.

6. Contents of the pack and other information

What Fenorol contains

The active substance is formoterol fumarate dihydrate. Each dose contains 12 micrograms of formoterol fumarate dehydrate.

The other excipient is lactose up to 25 mg per metered dose.

What Fenorol looks like and contents of the pack

The capsules are supplied in blisters of 10 capsules + 1 inhaler, 30 capsules + 1 inhaler, 60 capsules + 1 inhaler, 100 capsules + 1 inhaler, 120 capsules + 1 inhaler, 180 capsules + 1 inhaler and in HDPE bottles of 60 capsules + 1 inhaler, 120 capsules + 1 inhaler, 180 capsules + 1 inhaler.

The inhaler consists of a cap, mouthpiece, inhaler body, perforating system with 4 needles at each side. The push-bottoms are dark blue

Not all pack sizes may be marketed.

Inhaler CE

The device conforms with Directive 93/42/EEC

Marketing Authorisation Holder

{To be completed nationally}

Manufacturer

{To be completed nationally}

Fenorol is authorized in the Member States of the EEA under the following names:

Sweden <invented name> 12 mikrogram Inhalationspulver, hård kapsel

Germany <invented name> 12 Mikrogramm Hartkapseln mit Pulver zur Inhalation

Hungary <invented name> 12 mikrogramm inhalációs por kemény kapszulában

This leaflet was last revised in **2024-09-10**