

Histoleve

Fluticasone propionate, 50 mcg per spray

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Histoleve. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Histoleve is used for

Histoleve contains a corticosteroid called fluticasone propionate, which treats inflamed tissue. The tiny amounts sprayed into your nose help to reduce swelling and irritation.

Histoleve is used to prevent and treat seasonal allergic rhinitis (e.g. hay fever) in adults and adolescents aged 12 years and over.

Do not use in children under 12 years of age.

When you have rhinitis, the inside of your nose becomes swollen and itchy. This usually occurs during spring and summer when it is caused by breathing pollens from grasses or trees. This condition is called hay fever. Some people get problems all the year round and this is called perennial rhinitis. It is often due to house dust mites or animals such as cats or dogs.

When you spray Histoleve into your nose it helps to relieve the itching, sneezing and blocked or runny nose.

Ask your pharmacist or doctor if you have any questions or if you aren't

sure why Histoleve has been recommended for you.

Histoleve is not addictive.

Before you use Histoleve

When you must not use it

- Do not use Histoleve if you have ever had an allergic reaction to fluticasone propionate, an allergic reaction to any other corticosteroid or any of the ingredients listed at the end of this leaflet.

Read the side effects section to find out the symptoms of an allergic reaction.

- Do not use Histoleve after the expiry date printed on the pack. If you use it after the expiry date has passed, it may not work as well.
- Do not use Histoleve if the packaging is torn or shows signs of tampering.

If you're not sure whether you should be using Histoleve, talk to your pharmacist or doctor.

Before you start to use it

You must tell your Pharmacist or doctor if You:

- Are pregnant or planning to become pregnant
- Are breastfeeding
- Have recently had nasal ulcers, injury or surgery to your nose
- Have a tendency to nose bleeds
- Have or have recently suffered from a nasal infection in or around the nose
- Have a high temperature, cold or have been diagnosed with a sinus infection.
- Are taking ritinovir (used to treat HIV)

- Are using ketoconazole (used to treat infections)

Do not use with another steroid product, e.g. tablets, asthma or nasal inhaler, except on the advice of a healthcare professional.

Consult a healthcare professional if you have eye pain or visual disturbances.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when using Histoleve with other medicines.

How to use Histoleve

How much to use

The usual dose is two sprays into each nostril once daily, preferably in the morning.

Histoleve quickly starts to reduce inflammation and swelling in your nose, although it may take a few days to significantly improve symptoms. Therefore, to prevent the onset of symptoms, start to use Histoleve a few days before expected exposure to one of your 'usual' triggers.

It may take a few days for this medicine to work and it is **VERY IMPORTANT THAT YOU USE IT REGULARLY**. If you stop the treatment when you feel better your symptoms may return as the medication wears off.

If your symptoms include watery eyes and they trouble you, advise your doctor or pharmacist.

Once your symptoms have improved you may be able to halve the dose to one spray into each nostril once a day. If symptoms get worse again, the dosage may be increased to two sprays into each nostril once a day. Try to use the lowest dose to control your symptoms.

Do not use a larger dose or use your nasal spray more often than recommended in the instruction leaflet. Do not use more than 2 sprays in each nostril daily.

If after 7 days your symptoms have not improved, stop using the spray and speak to your doctor.

If after 7 days your symptoms have improved but not enough, speak to your doctor or pharmacist for advice.

Do not use in children under 12 years of age. Intranasal corticosteroids may cause children to grow more slowly.

Do not use for more than 6 months continuously without the advice of a doctor.

Do not use for more than 3 months after first opening.

Using the spray

If your product is new and you have not used it before, you should activate six sprays into the air before use.

1. Shake the bottle and remove the cap. Prime the bottle by pumping the spray a few times until a fine mist is produced.
2. Blow your nose gently.
3. Close one nostril and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright.
4. Start to breathe in slowly through your nose. While you are breathing in squirt a spray of fine mist into your nostril by pressing down firmly on the collar with your fingers.
5. Breathe out through your mouth. Repeat step 4 to take a second spray in the same nostril.

6. Remove the nozzle from this nostril and breathe out through your mouth.
7. Repeat steps 3 to 6 for the other nostril.

After first use, if you have not used the product for 5 days or more, discard the first 2 sprays.

Discard 3 months after first use.

Keep it clean

A clean spray nozzle helps ensure a full dose. Clean it weekly, or if it's clogged. Don't try to unblock nozzle with pin or sharp object that can damage it.

1. Remove spray nozzle by grasping at base and pulling up.
2. Rinse under running tap, and dry at room temperature.
3. Aim away from your face and gently replace spray nozzle until you hear a soft click.
4. Activate six sprays into the air before use.

If spray nozzle is clogged, soak in warm water. Then repeat steps 2 and 4.

If you take too much (overdose)

If you or someone else accidentally uses too much Histoleve on one occasion, there is nothing to worry about. However, if you use too much of it over a long time (months or years) you may start to get unwanted side effects inside your nose and body.

Discuss any worries you may have about this with your doctor or pharmacist.

In case of overdose or poisoning contact a doctor or a Poisons Information Centre (telephone Australia 131126; New Zealand 0800 764 766).

If you forget to use the spray

If you miss a dose, just use the next one when it is due.

While you are using Histoleve

Things you must do

Tell your doctor or pharmacist that you are using Histoleve if you are about to be started on any new medicines.

Tell your pharmacist or doctor if, for any reason, you have not used your medicine exactly as recommended.

Use Histoleve only in your nose.

Things you must not do

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Do not use Histoleve to treat any other conditions unless advised by your doctor to do so.

Side effects

Check with your pharmacist or doctor as soon as possible if you have any problems while using Histoleve, even if you do not think the problems are related to the medicine or are not listed in this leaflet.

See your doctor or pharmacist if you develop signs or symptoms of a nasal or sinus infection such as fever, pain or swelling, or discoloured nasal discharge.

Like other medicines, Histoleve can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and may need medical attention.

The most commonly reported side-effects are:

- dry or irritated nose or throat
- nosebleeds
- bad taste or smell
- headache
- sores in the nose

If any of these side effects persist, or are troublesome, see your doctor.

Stop using your spray and contact your doctor immediately if:

- You get new changes to your vision, including blurred vision, that develop after starting this product. There have been rare reports of eye problems such as cataracts, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) in people who have used large amounts of corticosteroids over a period of several years.
- You develop small holes (perforations) in the ridge inside the nose that separates the nostrils.
- You experience an allergic reaction.

If you think you are having an allergic reaction to Histoleve, TELL YOUR DOCTOR IMMEDIATELY or go to the emergency department at your nearest hospital.

Symptoms of an allergic reaction include skin rashes and itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your pharmacist or doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage

Store below 30 °C.

Discard 3 months after opening.

Do not freeze.

Keep this medicine where young children cannot reach it.

What Histoleve looks like

Histoleve is contained in a brown transparent glass container fitted with a metered dose manual pump. The glass bottle is packed in a carton. It contains a minimum of 120 sprays.

Ingredients

Histoleve contains the active ingredient, Fluticasone propionate. It also contains the following inactive ingredients: dispersible cellulose, glucose, polysorbate 80, benzalkonium chloride (preservative), phenylethyl alcohol (preservative), hydrochloric acid and purified water.

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