Histoleve

Active ingredient(s): *fluticasone propionate 50 µg per spray*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Histoleve. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Histoleve.**

Where to find information in this leaflet:

1. Why am I using Histoleve?
2. What should I know before I use Histoleve?
3. What if I am taking other medicines?
4. How do I use Histoleve?
5. What should I know while using Histoleve?
6. Are there any side effects?
7. Product details

1. Why am I using Histoleve?

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 aged 18 years and over.

Do not use in children under 12 years of age. Use only on medical advice in adolescents aged 12-17 years.

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.

2. What should I know before I use Histoleve?

Warnings

Do not use Histoleve if:

- you are allergic to fluticasone propionate or 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. Always check the ingredients to make sure you can use this medicine.
- the expiry date printed on the pack has passed. If you use it after the expiry date has passed, it may not work as well.
- 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.

Check with your doctor or pharmacist if you:

- 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 ketoconozole (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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Histoleve.

4. How do I 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 should 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. Use only on medical advice in adolescents aged 12 - 17 years. 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.

How to use Histoleve

Shake the bottle and remove the cap. The pump should be primed when used for the first time or if not used for more than 5 days by spraying a few times until a fine mist is produced.

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.

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 use too much Histoleve

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) or go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you forget to use the spray

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

5. What should I know while using Histoleve?

Things you should 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 should 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.

Looking after your medicine

Store below 30 °C.

Do not freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

in the bathroom or near a sink, or
in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard 3 months after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Common side effects

Common side effects	What to do
• Dry or irritated nose or throat • Nosebleeds • Bad taste or smell • Headache • Sores in the nose	**See your doctor if any of these side effects persist or are troublesome.**

Serious side effects

Serious side effects	What to do
• 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.	**Stop using the spray and contact your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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 doctor or pharmacist if you notice anything else that may be 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration (Australia) online at www.tga.gov.au/reporting-problems

or to Medsafe (New Zealand) at https://pophealth.my.site.com/carmreportnz/s/.

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

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Histoleve contains

Active ingredient (main ingredient)	fluticasone propionate
Other ingredients (inactive ingredients)	dispersible cellulose, glucose, polysorbate 80, benzalkonium chloride (preservative), phenylethyl alcohol (preservative), hydrochloric acid and purified water

Do not take this medicine if you are allergic to any of these ingredients.

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. (Aust R 470128).

Who distributes Histoleve

AFT Pharmaceuticals Pty. Ltd.
North Ryde, NSW, Australia

Email: customer.service@aftpharm.com

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