

Package leaflet: Information for the user
Budesonid Mylan 50 micrograms/dose nasal spray, suspension
Budesonide

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet

What is in this leaflet:

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

1. What Budesonid Mylan is and what it is used for

Budesonid Mylan belongs to a group of medicines called corticosteroids (commonly called steroids). It works by reducing inflammation inside your nose, relieving itching, sneezing and blocked up nose.

Budesonid Mylan is used to treat and prevent seasonal allergic rhinitis (e.g. hay fever), perennial allergic rhinitis and vasomotor rhinitis. When you have rhinitis the inside of your nose becomes swollen and itchy. This often occurs in the early summer when it is called hay fever. Some people have problems all year round when it is called perennial rhinitis. This is often due to house dust mites or animals such as cats or dogs. Some people suffer from inflammation of the lining of the nose due to overactivity of the nerves which supply the nose. This is called vasomotor rhinitis.

2. What you need to know before you use Budesonid Mylan

Do not use Budesonid Mylan

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

Warnings and precautions

Talk to your doctor before using Budesonid Mylan if any of the following applies to you:

- if you have pituitary (pea shaped structure in brain) and adrenal (glands in the kidneys) dysfunction and were receiving steroids previously, your doctor might conduct some relevant tests
- if you have been diagnosed with having a fungal or viral infection in your chest or throat
- if you have liver problems as this may increase the availability of Budesonid Mylan
- if you have tuberculosis (TB)

If you are a child under 18 years of age and have received the medicine for a long time, your doctor might monitor your growth and reduce the dose if required.

Many undesirable effects can occur with long term treatment with high doses like growth retardation, kidney glands (adrenal) suppression, eye problems, and psychological problems like anxiety, depression, aggression or sleep disorders and a disorder causing weight gain, moon face, obesity of face and trunk and other symptoms (Cushingoid syndrome).

If Budesonid Mylan comes into contact with your eyes, rinse with water immediately.

If you participate in sports and use chemical tests to check for steroids in your system, Budesonid Mylan may give a false positive result.

Other medicines and Budesonid Mylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including the following:

- ketoconazole and itraconazole (anti-fungal medicines), as they can increase the concentration of budesonide and therefore this combination should be avoided. If not possible, then the period between the intake of the two drugs should be as long as possible.
- oestrogens and contraceptive steroids, because they can increase the budesonide effects

Budesonid Mylan may also have a possible effect on test for diagnosing pituitary insufficiency.

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 or pharmacist for advice before taking this medicine.

Budesonid Mylan should only be used during pregnancy if the potential benefits outweigh the risks. In this case, the lowest possible dose for the shortest possible duration is recommended.

Budesonid Mylan can be used during breastfeeding.

Budesonide has been shown to pass in to breast milk, however, when used at the recommended dose it is not expected that budesonide will have any effect on your baby.

Driving and using machines

Budesonid Mylan does not affect your ability to drive or use machines.

3. How to use Budesonid Mylan

Always use this medicine exactly as your doctor or pharmacist has told you. Your dose will be adjusted according to your individual requirements. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children over 6 years of age: 4 sprays in each nostril in the morning. When a good result has been achieved your doctor may advise that this can be reduced to 2 sprays in each nostril.

You may have symptom relief within 24-36 hours after you have started treatment, but you may not feel the full effect until after a few days of treatment. You should therefore start treatment of seasonal allergic rhinitis before exposure to allergens, if possible.

Method of administration

Follow the instructions given below. Do not use your spray more often than recommended. If you have any problems tell your doctor or pharmacist. **Please note** before you use the nasal spray for the first time shake the bottle gently, remove the plastic cover and spray a few times in the air until a fine even mist comes out of the nozzle. You should also do this if you have not used the spray for a longer period of time. This time one spray in the air is enough.

Normal use

1. **Blow your nose gently. Shake the bottle. Remove the plastic cover.**
2. **Hold the spray bottle so that you can depress the plastic applicator.**
3. **Place the applicator into one of your nostrils and keeping your head tilted slightly forward spray in the recommended number of sprays. Repeat for the other nostril. NOTE: it is not necessary to inhale at the same time as spraying.**

4. Replace the plastic cover

Cleaning

It is helpful to clean the upper plastic parts occasionally. To do this, remove the plastic cover. Pull off the nasal applicator. Rinse the plastic cover and the applicator under luke-warm water. Let the parts dry in the air and then replace them. The spray unit should be cleaned if at any time the spray of medicine is not coming out as it should, after checking that the unit is primed. Any blockage should be removed by washing and not with a pin or other sharp object.

If you take more Budesonid Mylan than you should contact your doctor or nearest hospital emergency department immediately, take the container with you. It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.

If you forget to use Budesonid Mylan take the dose as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

If any of the following allergic reactions happen, stop taking Budesonid Mylan and tell your doctor immediately or go to your nearest hospital emergency department as you may need urgent medical treatment:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema). This uncommon side effect may affect up to 1 in 100 people.
- sudden signs of a severe allergy reaction (anaphylaxis) such as fever, fall in blood pressure, oedema (swelling of the skin) shortness of breath. This very rare side effect may affect up to 1 in 10 000 people.

Common side effects (may affect up to 1 in 10 people) include:

- nose bleed
- nasal irritation
- sneezing

Uncommon side effects (may affect up to 1 in 100 people) include:

- skin rash, itching, lumpy rash (hives), blistering of the skin

Rare side effects (may affect up to 1 in 1 000 people) include

- corticosteroid effects including adrenal suppression and growth retardation, particularly at high doses for prolonged periods (see section 2, Warnings and precautions for more information)

Very rare side effects (may affect up to 1 in 10 000 people) include:

- perforation of the membrane separating the nostrils (the nasal septum)
- sores on the lining of the nose
- Voice disorder characterized by hoarseness

Not known (frequency cannot be estimated from available data)

- cataract (clouding of the lens in the eye).
- glaucoma (increased pressure in the eye)

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Budesonid Mylan

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

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month. Shelf life after opening: 2 months.

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 Budesonid Mylan contains

- The active substance is budesonide (50 micrograms/dose).
- The other ingredients are disodium edentate, glucose, hydrochloric acid, potassium sorbate (preservative), microcrystalline cellulose, sodium carboxymethyl cellulose, polysorbate, purified water.

What Budesonid Mylan looks like and contents of the pack

Budesonid Mylan is available in amber glass bottles with a nasal spray unit containing nasal spray 50 micrograms/dose: 10 ml (200 sprays) and 2 x 10ml (400 sprays).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
[to be completed nationally]

Manufacturer:
Gerard Laboratories
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden	Budesonid Mylan 50 mikrog/dos nasspray, suspension
Luxembourg	Rhinobudesonide Mylan Spray 50mcg
The Netherlands	Budesonid Nevel Mylan 50, neusspray 1mg/ml
Portugal	BUDESONIDE Mylan Genericos 50µg suspensao para pulverizacao nasal

This leaflet was last revised in 2014-09-16