Budesonide 50 micrograms/ dose nasal spray, suspension

Module 1.3.1.3 Package Leaflet
(English version)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Budesonide PH&T 50 nasal spray
Budesonide

Read all of this leaflet carefully before you start taking this medicine.

• Keep this leaflet. You may need to read it again.
• If you have further questions, ask your doctor or your pharmacist.
• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

In this leaflet:
1. What “Budesonide PH&T 50 nasal spray” is and what it is used for.
2. Before you take “Budesonide PH&T 50 nasal spray”.
3. How to take “Budesonide PH&T 50 nasal spray”.
4. Possible side effects.
5. How to store “Budesonide PH&T 50 nasal spray”.
6. Further information.

1. WHAT “BUDESONIDE PH&T 50 NASAL SPRAY” IS AND WHAT IT IS USED FOR

“Budesonide PH&T 50 nasal spray” contains the active ingredient budesonide which belongs to a group of medicines called corticosteroids. These reduce inflammation and swelling and so relieve congestion, itching, sneezing, irritation and discomfort.

“Budesonide PH&T 50 nasal spray” is used to treat allergies such as hay fever and rhinitis (inflammation of the inside of the nose causing congestion, sneezing or a runny nose). It is also used to treat nasal polyps which are small growths on the lining inside the nose.

2. BEFORE YOU TAKE “BUDESONIDE PH&T 50 NASAL SPRAY”

Do not take “Budesonide PH&T 50 nasal spray”:
• If you are allergic (hypersensitive) to budesonide
• If you are allergic to any of the other ingredients in this nasal spray (these are listed in Section 6, Further information)

Take special care with “Budesonide PH&T 50 nasal spray”:
• If you have a cold or chest infection. Talk to your doctor if this applies to you.
• If you have been taking this medicine continuously for a long time. Your doctor will want to examine the lining inside your nose at least once a year.
• If you have been taking high doses of this medicine for a long time. Your doctor may prescribe steroid tablets for you during periods of stress (such as if you have an infection) or before an operation.
• If you are a child and you have been taking high doses of this medicine for a long time. Your doctor will want to monitor your height.
• If you are already taking steroid tablets. Your doctor may slowly reduce the number of tablets that you take when you start using this nasal spray. If you experience any unusual symptoms as a result of this, tell your doctor.

Pregnancy and breast-feeding
Do not use “Budesonide PH&T 50 nasal spray” if you are pregnant unless your doctor tells you to. If you become pregnant whilst using this medicine you should contact your doctor as soon as possible.

Do not use “Budesonide PH&T 50 nasal spray” if you are breastfeeding. However, if your doctor tells you to take this medicine, you should stop breastfeeding.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Driving and using machines
“Budesonide PH&T 50 nasal spray” has no known effect on the ability to drive and use machines.

3. HOW TO TAKE “BUDESONIDE PH&T 50 NASAL SPRAY”

“Budesonide PH&T 50 nasal spray” should only be used by the nasal route.
Always take “Budesonide PH&T 50 nasal spray” exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure. The usual doses are given below.

Treatment of allergies such as hay fever and rhinitis (inflammation of the inside of the nose).

Adults and children over 6 years

There are two ways of using “Budesonide PH&T 50 nasal spray”:

• Once daily: The usual starting dose is 4 sprays into each nostril every morning.
• Twice daily: The usual starting dose is 2 sprays into each nostril every morning and evening.

When your symptoms improve, your doctor may reduce the dose.
You should not take more than 400 micrograms (8 sprays) in a day.

At the start of treatment with “Budesonide PH&T 50 nasal spray”, your doctor may also prescribe other medicines to help control streaming eyes and a blocked nose.

It may take a few days for your medicine to start working to relieve your symptoms.
Don’t give up; continue taking the medicine as you have been told to. If you still cannot feel any benefit after two weeks of taking your medicine, contact your doctor.

If there is no improvement after 3 months of treatment, your doctor will stop your treatment with “Budesonide PH&T 50 nasal spray”.
Treatment of nasal polyps.

The usual dose is 2 sprays into each nostril every morning and evening.

Instructions for use:

Before using “Budesonide PH&T 50 nasal spray” for the first time, you must prime the nozzle (i.e. fill it with the medicine). To do this, shake the bottle and remove the protective cap. Then hold the bottle upright as shown and pump the nozzle up and down several times, spraying into the air until an even mist is seen. “Budesonide PH&T 50 nasal spray” is now ready to use.

1. **Blow your nose.** Shake the bottle. Remove the protective cap.
2. Hold the bottle as shown in the pictures.
3. Tilt your head back and insert the tip of the nozzle into your nostril, as shown. Spray into the nostril. Note: it is not necessary to breathe in at the same time as you spray.
4. Spray into the other nostril in the same way.
5. Wipe the nozzle with a clean tissue and replace the protective cap. Store the bottle in an upright position.

Cleaning the nozzle:

You should clean the plastic nozzle regularly, as follows:

Remove the nozzle by pushing the “wings” upwards.

Rinse the nozzle and the protective cap and leave to dry.

After cleaning, the nozzle must be primed (filled with medicine again) before use.

**If you take more “Budesonide PH&T 50 nasal spray” than you should**, consult your doctor or pharmacist straight away.

**If you forget to take “Budesonide PH&T 50 nasal spray”**, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, just remember to take the next one at the usual time.

**Do not take a double dose to make up for the forgotten dose.**

**If you stop taking “Budesonide PH&T 50 nasal spray”**, the symptoms may return that you had before starting treatment.

4. POSSIBLE SIDE EFFECTS

Like all medicines, “Budesonide PH&T 50 nasal spray” can cause side effects although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have also been reported:
Very common

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<tr>
<td>Common</td>
<td>more than 1 out of every 100 but less than 1 out of every 10 people</td>
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<td>Uncommon</td>
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<td>Rare</td>
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<td>Very rare</td>
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**Disorders of the Respiratory and Thoracic tracts**

**Very common:** Irritation inside the nose, runny nose at the beginning of the treatment, nose crusting and sometimes nose bleeds

**Common:** Sneezing soon after the start of treatment, breathlessness, hoarseness, wheezing, and nose pain.

**Very rare:** Cases of ulcers in the nose and a hole in between the two nostrils have been reported.

**Disorders of the gastrointestinal tract**

**Common:** Dry throat

**Disorders of the skin and adjacent tissues**

**Rare:** Skin rashes such as urticaria or “nettle rash” (a skin rash with swellings and heavy itching), dermatitis (rash with reddening of the skin and itching), pruritus (itching), and angioedema (temporary swelling in the skin and itching).

**General disorders and administration site conditions**

**Uncommon:** Candidiasis (a fungal infection) and atrophy (wasting away) of the inside of the nose, in particular after long-term use.

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor pr pharmacist.

**5. HOW TO STORE “BUDESONIDE PH&T 50 NASAL SPRAY”**

Keep out of the reach and sight of children.

Do not use “Budesonide PH&T 50 nasal spray” after the expiry date which is stated on the carton.

Do not store your medicine above 25°C. Do not refrigerate or freeze. Store in the original package.

Use within 3 months after opening the bottle. You may find it helpful to write on the leaflet when you first open the bottle.
6. FURTHER INFORMATION

What “Budesonide PH&T 50 nasal spray” contains:
• The active substance is budesonide 1mg/ml
• The other ingredients are sodium carboxymethylcellulose, microcrystalline cellulose, potassium sorbate, glucose, polysorbate 80, disodium edetate, hydrochloric acid and purified water.

What “Budesonide PH&T 50 nasal spray” looks like and contents of the pack:
Your medicine is an aqueous suspension containing 1 mg of budesonide per ml of suspension. Each spray delivers 50 micrograms of budesonide. One 10ml bottle contains 200 doses. The suspension is contained in an amber glass bottle with a plastic nozzle. Each carton contains one or two bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
PH&T S.p.A.
Via Ariosto, 34
20145 Milan (Italy)

Manufacturer:
Mipharm S.p.A.
Via B. Quaranta, 12
20141 Milan (Italy)

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