BUDENIDE NASAL SPRAY

Budesonide (0.128%w/v)

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

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Budenide Nasal Spray against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

What Budenide Nasal Spray is used for

Budenide Nasal Spray is indicated for seasonal allergic and allergic/ non-allergic all year round rhinitis (inflammation on nose mucous membrane). It is also used for the treatment of nasal polyps (noncancerous growth) and the reduction of risks of the development of new polyps after surgical removal of polyps.

How Budenide Nasal Spray works

Budenide Nasal Spray contains the active ingredient Budesonide. Budesonide is glucocorticosteroid with high local anti-inflammatory effects and block the substance that cause allergic reaction to our body.

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use Budenide Nasal Spray

-When you must not use it

Do not use Budenide Nasal Spray if:

- You are allergic (hypersensitive) to Budesonide or to any of the other ingredients in this medicine.

-Before you start to use it

Tell your pharmacist or doctor:

- If you have liver problem.

Pregnancy and breast feeding:

- Budenide Nasal Spray should not be used during pregnancy unless clearly necessary. If you have informed your doctor or pharmacist already, follow his/her instructions carefully.
- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, trying to get pregnant, think you may be pregnant or if you are breast-feeding because other glucocorticosteroids are found in human milk, caution should be exercised when Budenide is used by nursing women.

-Taking other medicines

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

How to use Budenide Nasal Spray

-How much to use

Always use Budenide Nasal Spray as directed by your doctor or pharmacist.

If you have seasonal allergic rhinitis (hay fever), you should try to start the treatment with Budenide Nasal Spray before the allergic season starts.

Adults and children 6 years of age and above:

The recommended starting dose is 256 µg daily.

When good effect has been achieved, reduce dose to the smallest amount necessary to control the symptoms.

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

-When to use it

The dose can be takem once daily in the morning or divided into two times morning and evening.

-How long to use it

Use Budenide Nasal Spray as advised by your doctor or pharmacist. If condition worsens or does not improve after regular use of this product as directed, consult a doctor.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

If, by mistake on a few occasions you use more than you should, do not worry. If you accidentally swallowed, talk to your doctor or go to the hospital as soon as possible.

If symptoms of chronic overdose occur, nasal corticosteroids should be discontinued slowly.

Use of excessive doses or long-term treatment with glucocorticosteroids may lead to signs or symptoms of hypercorticism (Cushing's syndrome or an excess level of steroids hormone in your body),

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suppression of hypothalamic, pituitary, adrenal gland function and/or suppression of growth in children.

While you are using Budenide Nasal Spray

-Things you must do

If you are about to start taking on any other new medicine, medicines obtained without prescription and herbal medicines, tell your doctor or pharmacist that you are using Budenide Nasal Spray.

-Things you must not do

Do not take more than the recommended dose unless your doctor or pharmacist tells you to.

-Things to be careful of

Physicians should closely follow the growth of the children taking glucocorticosteroids for longer term by any route, and weigh the benefits of the glucocorticosteroids therapy against the possibility of growth suppression.

Side effects

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

The following adverse drug reactions may occur. Local symptoms such as:

- Dry nose
- Sneezing and nasal stinging immediately after the use of the nasal spray
- Slight bloody secretion and nose bleeding.
- Skin reactions i.e. hives, rash, skin inflammation and angioedema (swelling beneath the skin).

Other most frequently reported cases are throat irritations and increased cough. Extremely rare cases of ulcerations of the mucous membrane and nasal septal (wall that separates the nasal cavity into the two nostrils) perforation have been reported following use of intranasal glucocorticosteroids.

If any side effect becomes severe, or you notice any side effect not listed here, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Budenide Nasal Spray

-Storage

Store below 30°C.
Protect from strong light.
Keep container well closed.
Keep out of reach of children.

For external use only.

-Disposal

Dispose the medicine after the expiry date. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

-What it looks like

Budenide Nasal Spray is a white to off-white suspension.

Budenide Nasal Spray available in plastic spray pump bottle of 15ml.

-Ingredients

-Active ingredient(s):
Each bottle contains Budesonide 0.128% w/v (Each spray is 64 µg/ dose in 120 doses pack size)

-Inactive ingredients:
Dextrose, Potassium Sorbate, Disodium Edetate, Microcrystalline Cellulose dan Carboxymethyl Cellulose Sodium, Polysorbate 80, Hydrochloric acid and Purified Water.

-MAL number:

MAL20051362AZ

Manufacturer

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Product Registration Holder

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