

BESONIN AQUA NASAL SPRAY 64MCG/DOSE

Budesonide 64mcg/dose

What is in this leaflet

1. What Besonin Aqua is used for
2. How Besonin Aqua works
3. Before you use Besonin Aqua
4. How to use Besonin Aqua
5. While you are using it
6. Side effects
7. Storage and Disposal of Besonin Aqua
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Besonin Aqua is used for

Besonin Aqua is used for running nose, nasal congestion, sneezing and/or itching in the nose caused by allergy and also for so-called vasomotor rhinitis where the cause may be e.g. smoke or perfume.

Besonin Aqua is also used for polyps in the nose and after surgery for polyps in order to reduce the risks of the development of new polyps.

How Besonin Aqua works

Besonin Aqua is a cortisone preparation that suppresses inflammation and allergic reactions in the nose.

Before you use Besonin Aqua

- When you must not use it

Do not use Besonin Aqua if you are allergic (hypersensitive) to budesonide or to any of the other ingredients of Besonin Aqua.

- Before you start to use it

Take special care with Besonin Aqua

- avoid Besonin Aqua coming into contact with the eyes. If you get it in your eyes, rinse them immediately with water.
- talk to your doctor before you start using Besonin Aqua if you have any of the following conditions:
 - fungal or herpes infection in the nose
 - tuberculosis
 - severe liver disease

Long-term treatment with high doses can cause serious cortisone side effects. In children this may manifest itself as retarded growth.

- 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.

How to use Besonin Aqua

- How much to use

Always use Besonin Aqua exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

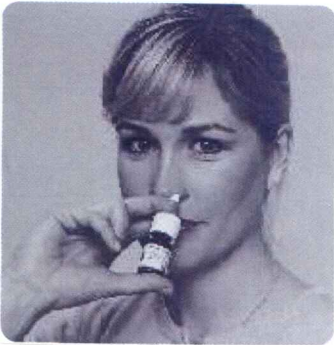
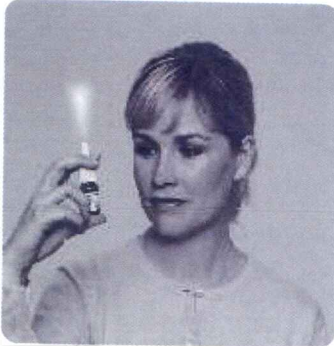
If you have seasonal allergic rhinitis (hay fever), you should try to start the treatment with Besonin Aqua a few days before the allergy season starts. You should gain the full effect within a few days, but you may feel some relief after just a few hours. Use of Besonin Aqua by children should take place under the supervision of an adult so that the spraying is carried out correctly and that the dosage is in accordance with the doctor's prescription.

Instructions for use

Before you use a new bottle of Besonin Aqua, you must prime the pump by shaking the bottle and spraying into the air until there is an even mist. If you do not use the nasal spray every day, the pump must be primed in the same way again, but this time it is sufficient to spray just once into the air.

1. Blow your nose
Shake the bottle.
Remove the protective cap.
2. Hold the bottle as shown in the pictures.
3. Insert the tip into one nostril and spray the prescribed number of doses. Follow the same procedure for the other nostril
4. Replace the protective cap.

Do not exceed the dosage!



- When to use it

Use Besonin Aqua as prescribed by your doctor or pharmacist.

- How long to use it

Use Besonin Aqua as advised by your doctor or pharmacist.

- If you forget to use it

On occasion it is not necessary to make up for the missed dose. Take the next dose as usual.

- If you use too much (overdose)

If you have used too much Besonin Aqua on a single occasion you should not experience any unpleasant effects. If you have any questions after taking too large a dose, always contact a doctor or hospital for assessment of the risk and advice.

While you are using it

- Things you must do

If you are about to be started on any new medicine, remind your doctor that you are using Besonin Aqua.

Tell any other doctors, dentists, and pharmacists who treat you that you are using Besonin Aqua.

- Things you must not do

Do not stop using Besonin Aqua unless advised by your doctor or pharmacist.

- Things to be careful of

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Experience of use during pregnancy does not indicate any increased risk of malformations. Nevertheless, talk to your doctor if you use Besonin Aqua more than occasionally during pregnancy.

Budesonide passes into breast-milk.

However, a risk of effects on the breast-fed infant is considered unlikely with therapeutic doses of Besonin Aqua.

Besonin Aqua may be used while breast-feeding.

Driving and using machines

Besonin Aqua does not affect the ability to drive or use machines.

Side effects

Like all medicines, Besonin Aqua can cause side effects, although not everybody gets them. The side effects that may occur are usually mild and last only a short time.

Common: Irritation in the nose, nose-bleeding.

Uncommon: Allergic swelling, rash, itching, nettle rash, inflammation in the skin, angioedema*.

Very rare: Ulcers on the nasal mucous membrane, perforation of the wall separating the nostrils, severe allergic reaction.

* Stop taking Besonin Aqua and contact a doctor immediately if you have any of the following symptoms (angioedema):

- swelling of the face, tongue or throat
- difficulties in swallowing
- nettle rash and breathing difficulties

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, 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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Besonin Aqua

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C. Do not freeze.

Do not use after the expiry date.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Date of Revision

19/05/2016

Serial number

BPFK(Rx/x)xxxxxx/xxxxx

Product description

- What it looks like

Besonin Aqua Nasal Spray is a metered-dose, manual-pump spray formulation containing a micronized suspension of budesonide in an aqueous medium. It appears as a white to almost white suspension.

- Ingredients

- Active ingredient

Budesonide

- Inactive ingredients

• Potassium Sorbate

• Dextrose Anhydrous

• Microcrystalline Cellulose and
Carboxymethyl Cellulose Sodium

• Polysorbate 80

• Edetate Disodium

• Hydrochloric Acid

• Purified water

- MAL numbers

MAL

Manufacturer

SYNMOSA BIOPHARMA
CORPORATION, Synmosa Plant
No.6, Kuang Yeh 1st Road, Hu-Kuo
Hsiang, Hsin-Chu Ind. Park, Hsin Chu
Hsien, Taiwan, R.O.C.

Product Registration Holder

Rigel Pharma Sdn Bhd
3rd Floor, Apex Healthcare Building,
No.2, Jalan SS 13/5, 47500 Subang Jaya,
Selangor, Malaysia