

# BESONIN AQUA NASAL SPRAY

Budesonide (50 mcg/dose, 100 mcg/dose)

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## What Besonin is used for

Besonin nasal spray contains the active ingredient budesonide. It belongs to a group of medicines known as corticosteroids, frequently referred to as 'steroids'.

Besonin 50, 100 mcg/spray is normally used to prevent and treat seasonal and perennial (occurring throughout the year) allergic rhinitis (inflammation of the inside of the nose) and vasomotor (nonallergic) rhinitis.

## How Besonin works

Besonin works by reducing the swelling and irritation in the lining of the nose. It relieves the symptoms of blocked nose, runny nose, itchy nose and sneezing.

Your doctor or pharmacist, however, may recommend Besonin for another purpose.

Besonin 50, 100 mcg/dose are available only on prescription from your doctor.

## Before you use Besonin

### - When you must not use it

Do not use Besonin if you have an allergy to:

- any medicine containing budesonide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Besonin after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor or pharmacist.

### - Before you start to use it

Tell your doctor if you are allergic to:

- any other corticosteroid medicines
- any other medicines, foods, preservatives or dyes

Tell your doctor if you have chicken pox or measles.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using Besonin.

### - Taking other medicines

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

Your doctor and pharmacist have more information on medicines to be careful with while using Besonin with other medicines.

## How to use Besonin

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

## Instructions for use

1. Shake the bottle well before use. Remove the dust cap from the nasal applicator.
2. Prime for initial use by putting two fingers on the shoulders of the spray pump unit and place your thumb on the bottom of the bottle. Press upward with thumb, release, and repeat until a fine mist appears (5-10 sprays). Now your pump is primed and ready to use. If 2 or more days have elapsed since the last use, the pump should be reprimed with 2

sprays or until a fine mist appears.

3. Gently blow nose to clear nostrils.
4. Place the spray tip 0.5 cm to 1 cm into one nostril. Hold bottle vertically upright, allowing spray tip to aim toward the back of the nose. Close other nostril with finger, rapidly press once with thumb and sniff gently at the same time.
5. Repeat in the other nostril.
6. Replace the dust cap.

- How much to use

It is important that you use Besonin exactly as directed by your doctor. Do not use more than recommended; using more or less may make your symptoms worse.

The usual dosage of for adults and children over 6 years is as below:

- 50 mcg/dose: one spray into each nostril twice a day
- 100 mcg/dose: one spray into each nostril daily.

Do not use Besonin 50, 100 mcg/dose in children under 6 years of age.

Your doctor may tell you to use different doses to these. If so, follow their instructions.

You must use Besonin for your nose only. If you find it difficult to use your spray, talk to your doctor or pharmacist.

Besonin should be shaken before use.

- When to use it

Use your medicine at about the same time each day. Using it at the same time each day will have the best effect. It will also help you remember when to use it.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Besonin for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor, pharmacist for advice if you think that you or anyone else may have used too much Besonin. Do this even if there are no signs of discomfort or poisoning.

High doses of corticosteroids may lead to suppression of the hypothalamic-pituitary-adrenal (HPA) axis function (central stress response system).

**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.

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

If you become pregnant while taking Besonin, tell your doctor immediately.

- Things you must not do

Do not use Besonin to treat any other complaints unless your doctor tells you to.

Do not give your Besonin to anyone else, even if their symptoms seem similar to yours.

- Things to be careful of

Intranasal corticosteroids may affect growth rates in children. Talk to your doctor for more information.

Make sure your doctor knows if you are pregnant or breastfeeding, or if you have a recent exposure to chickenpox or measles.

Avoid getting this medicine in your eyes.

**Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Besonin. This medicine helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. You

may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nose irritation
- nose bleeds
- cough
- nausea
- dry nose
- sore throat
- hoarseness
- bad taste

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

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](http://portal.bpfk.gov.my) (Consumers → Reporting).

### Storage and Disposal of Besonin

#### - Storage

Keep Besonin in a cool dry place where the temperature stays below 25°C.

Do not store Besonin in the refrigerator.

Do not store Besonin or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep the bottle in an upright position.

Once you have opened your spray, you should not use this particular bottle for more than six months. Write down the date that you opened the bottle on the label or the box.

#### - 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.

### 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

Besonin 50 mcg/dose:

MAL08082703A

Besonin 100 mcg/dose:

MAL08082702A

### Product Registration Holder

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

### Manufacturer

Synmosa Biopharma Corporation  
No.6, Kuang Yeh 1<sup>st</sup> Road,  
Hsin-Chu Ind. Park, Hsin Chu Hsien,  
Taiwan, R.O.C.

### Date of Revision

17/11/2015

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