

Talgan Nebulizer suspension

Budesonide (0.25 mg/ml, 0.5 mg/ml)

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What Talgan is used for

Talgan is used for the treatment of asthma.

How Talgan works

Talgan contains a medicine called budesonide. This belongs to a group of medicines called corticosteroids. It works by reducing and preventing swelling and inflammation in the airways caused by asthma.

Before you use Talgan

When you must not use it

In case of allergy or hypersensitivity to the Budesonide or to any of the other ingredients of Talgan.

Pregnancy and lactation

Do not take Talgan if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Talgan if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Tell your doctor or pharmacist if:

- You have a lung infection.
- You have a cold or chest infection.
- You have liver problems.

- 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.

This is because Talgan can affect the way some medicines work and some medicines can have an effect on Talgan.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroid medicines.
- Medicines to treat fungal infections (such as itraconazole and ketoconazole).

How to use Talgan

- Always use Talgan exactly as your doctor, nurse or pharmacist has told you. Ask one of them for advice if you are not sure.
- The solution in a single dose unit must be put into a nebuliser and made into a fine mist before it can be breathed in. It is then inhaled through a face mask or mouthpiece.
- Your asthma may improve within 2 days. However, it can take up to 4 weeks for the medicine to have its full effect. It is important to use Talgan every day, even if you have no asthma symptoms at the time.

Note: Do not use an ultrasonic nebuliser with Talgan.

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults:

1-2mg twice daily

Children:

0.5-1mg twice daily

For maintenance treatment, the number of doses varies and should be the lowest

possible dose. Recommended doses are:

Adult:

0.5-1mg twice daily

Children:

0.25-0.5mg twice daily

Following a single dose, an effect may be expected after a few hours. The full therapeutic effect is only achieved after a few weeks of treatment.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Talgan for as long as your doctor recommends.

- 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)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Talgan.

Tell your doctor immediately if you become pregnant while taking this medication.

After using Talgan, your need to:

- rinse the mouth out with water after inhaling the prescribed dose to minimise the risk of oropharyngeal thrush
- wash the facial skin with water after using the face mask to prevent irritation

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Talgan to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Talgan is not likely to affect your ability to drive or use any tools or machines.

Side effects

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

If either of the following happens to you, stop using Talgan and talk to your doctor immediately:

Common: Fungal infection in the mouth and throat, hoarseness, cough, throat irritation, irritation in the mouth and difficulty in swallowing.

Uncommon: Cataracts (clouding of the lens in the eye), feeling anxious, depression, and muscle spasm.

Rare: Allergic reaction such as itching, rash, bruising, inflammation, redness of the skin and/or skin eruption and swelling. Suppression of your adrenal gland (a small gland next to the kidney) and slowing of growth in children and adolescents can also occur.

Feeling restless, nervous, over-excited or irritable (these effects are more likely to occur in children).

Bronchospasm (tightening of the muscles in the airway resulting in wheezing) and difficulty in speaking.

Not known: glaucoma (buildup of pressure within the eye), sleeping problem, aggression and increased motor activity

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 <http://npra.moh.gov.my> (Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Talgan

- Storage

Keep in a safe place, out of the reach and sight of children.

Do not store above 30°C. Store Talgan in their original carton and pouch, and protect from light.

Once a pouch has been opened, store the pouch below 30°C and protect from light. The single dose units inside the opened pouch should be used within 3 months. **Note:** It is best to mark the opening date on the pouch to help you remember.

Once the plastic container has been opened, Talgan should be used immediately. If only some of the suspension is used, the remaining suspension in the single dose unit should be thrown away immediately.

- Disposal

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

White to off-white suspension filled in plastic single dose units. The solution must be nebulised (made

into a fine mist) before it can be breathed in.

- Ingredients

- Active ingredient(s)
Talgan Nebulizer suspension
0.5mg/2ml

Each ml nebuliser suspension contains 0.25mg of Budesonide

Talgan Nebulizer suspension
1mg/2ml

Each ml nebuliser suspension contains 0.5mg of Budesonide

- Inactive ingredients
Disodium edetate, Sodium chloride, Polysorbate 80 (Tween 80), Citric acid anhydrous, Sodium citrate, Water for injection

- MAL numbers:

Talgan Nebulizer suspension
0.5mg/2ml
MALXXXXXX

Talgan Nebulizer suspension
1mg/2ml
MALXXXXXX

Manufacturer

Genetic S.p.A,
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Product Registration Holder

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