

DALMAN® AQ NASAL SPRAY

Fluticasone propionate 50 micrograms

Active Substance: 100 mg spray consists of 50 micrograms of fluticasone propionate

Excipients: Dextrose, Microcrystalline cellulose and carboxymethyl cellulose sodium (Avicel RC591), Benzalkonium chloride, Polysorbate 80, Disodium hydrogen phosphate, Citric acid, Purified water

Read all of these leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dalman is and what it is used for
2. What you need to know before you take Dalman
3. How to take Dalman
4. Possible side effects
5. How to store Dalman

1. What Dalman is and what it is used for

Dalman AQ Nasal Spray (called ‘Dalman’ in this leaflet) contains a medicine called fluticasone propionate.

Each bottle of Dalman contains 120 actuations in each bottle.

This belongs to a group of medicines called cortico-steroids. Corticosteroids are not the same as anabolic (constitutive) steroids used illegally by some bodybuilders and athletes. These two kinds of drugs are completely different. Corticosteroids are used to reduce and prevent symptoms of allergic reactions when applied directly to the nostril.

DALMAN is used in adults and children above 4 years of age in the treatment and prevention of seasonal allergic rhinitis including hay fever and indications of unseasonal rhinitis (shown below).

- Sneezing
- Itching, nasal discharge
- Clogged nose
- Pressure and pain around the eyes and nose (sinuses)

2. What you need to know before you take

Do not take Dalman if:

- You are allergic to fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Take special care with Dalman

- If you are pregnant or planning to get pregnant
- If you are breastfeeding
- If you have or recently had an infection in your nose
- If you are told that your adrenal gland is malfunctioning
- If you have ever had an operation on your nose.

An increase in intraocular pressure has rarely been reported following Dalman administration.

If these warnings apply to you, even at any time in the past, please consult your doctor

Taking Dalman with food and drink

No data

Pregnancy

Consult your doctor or pharmacist before taking this medicine,

If you are pregnant, use DALMAN if the benefits outweigh the potential risks.

Lactation

Consult your doctor or pharmacist for advice before taking this medicine,

Since it is not known whether DALMAN has passed on to the milk, you should be careful when using DALMAN.

Driving and using machines

Dalman is not likely to affect you being able to drive or use any tools or machines.

Other medicines and Dalman

In some cases fluticasone propionate administered intranasally may not be suitable for use with other medicines (eg HIV / AIDS or oral fungicides). If you are using a medicine called ritonavir, you should not use fluticasone propionate without consulting a doctor. Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other prescribed or non-prescribed medicines.

3. How to take Dalman

It takes a few days for this medicine to work. So keep using it, even though you may not feel better straight away. Even if you feel better, do not stop using Dalman unless your doctor tells you.

If your symptoms do not improve after regular use or if it gets worse, ask your doctor to tell you what to do.

How much to use - adults and children (aged 12 and over)

- The usual starting dose is 2 sprays into each nostril once a day, preferably in the morning.
- The most you would use over 24 hours is normally 8 sprays (4 sprays per nostril).

- As you become better, your doctor may ask you to use a increase dose - two spray into each nostril twice a day (in the morning and in the evening).

How much to use – children aged 4 to 11 years

- The usual starting dose is one spray into each nostril once a day, preferably in the morning.
- Your doctor may ask you to use a increase dose - one spray into each nostril twice a day (in the morning and in the evening).
- The most you would use over 24 hours is normally 4 sprays (2 sprays per nostril).

Preparing your spray

Each spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray.

A new spray (or one that has not been used for a few days), may not work first time. You need to ‘prime’ the spray by pumping the spray a few times until a fine mist is produced.

1. Hold the bottle as shown and make sure it is pointed away from you.
2. Put your forefinger and middle finger on the collar either side of the nozzle and put your thumb underneath the bottle.
3. Keep your thumb still, and press down with your fingers to pump the spray.



- If the spray does not work and you think it may be blocked, you will need to clean it. Please see the section below, **Cleaning your spray**.
- Never try to unblock or enlarge the tiny spray hole with a pin or other sharp object. This will damage the way the spray works.

Using your spray

- 1 Shake the bottle and take off the dust cap.
- 2 Blow your nose gently.
- 3 Close one nostril with your finger as shown, and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright. Hold the bottle as shown.



- 4 Start to breathe in slowly through your nose. While you are breathing in press down firmly on the collar with your fingers. A spray of fine mist will go into your nostril
- 5 Breathe out through your mouth.
- 6 Repeat step 4 to use a second spray in the same nostril.
- 7 Remove the nozzle from this nostril and breathe out through your mouth.
- 8 Repeat steps 3 to 6 for your other nostril.
- 9 After using your spray, wipe the nozzle carefully with a clean tissue or handkerchief, and replace the dust cap.

Cleaning your spray

Clean your spray at least once a week, or more often if it gets blocked.

- 1 Take the dust cap off by gently squeezing the ribbed sides between your finger and thumb and lifting it off. Do not twist it off.
- 2 Pull upwards on the white collar to remove the nozzle.
- 3 Soak the nozzle and dust cap in warm water for a few minutes.
- 4 Then rinse under a running tap.
- 5 Shake off the excess water and let them dry in a warm place.
- 6 Put the nozzle back on the spray.
- 7 'Prime' the bottle as described in the section above, **Preparing your spray**.

If you use more Dalman than you should

Tell your doctor if you use more than you were told to.

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.

Different age groups:Use in Children

Do not use in children under 4 years old.

Elderly patients

Dose adjustment is unnecessary in elderly patients

Special use cases:

No data

If you have an impression that the effect of Dalman is too strong or weak, talk to your doctor or pharmacist.

If you use more Dalman than you should

Tell your doctor if you accidentally use more than you were told.

If you forget to use Dalman

If you miss a dose, just use the next dose when it is due. Do not take a double dose to make up for the forgotten dose.

If you stop taking Dalman

Do not stop treatment even if you feel better, unless your doctor tells you to stop. If you do stop, the symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

You should stop taking Dalman and get IMMEDIATE medical help if you experience symptoms such as:

A small number of people get allergic reactions to Dalman, which can develop into a more serious, even life-threatening problem if not treated. Symptoms include;

- Sudden wheezing and chest pain or squeeze
- Swelling around the face, mouth or tongue
- Skin rashes or redness

Side effects are classified as below:

Very common: At least 1 in 10 people.

Common: Less than 1 in 10 people, more than 1 in 100 people.

Not common: Less than 1 in 100 people, more than 1 in 1000 people.

Rare: Less than 1 in 1.000 people, more than 1 in 10.000 people.

Very rare: Less than 1 in 10.000 people.

Unknown: Cannot be estimated from the available data

Other side effects include:

Very common (may affect more than 1 in 10 people)

- Nose bleeds.

Common (may affect up to 1 in 10 people)

- Headache.
- Unpleasant taste.
- Unpleasant smell.
- A dry or painful nose or throat.

Very rare (may affect up to 1 in 10,000 people)

- Allergic reactions
- Blindness in the eye (cataract), eye pressure increase (glaucoma) that can cause vision problems. This has occurred in patients who have been using eye problems for a long time
- The formation of small holes in the nose separating the nostrils (perforation)

If you experience any side effects not mentioned in these instructions for use inform your doctor or pharmacist.

5. How to store Dalman

Keep out of the sight and reach of children.

- Protect from frost and light.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

Marketing Authorisation Holder

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. Sok. 7/3

Balgat – Ankara/Turkey

Manufacturer

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