

Package Leaflet: Information for the user

Zomig Nasal 2.5 mg/dose and 5 mg/dose nasal spray, solution zolmitriptan

Read all of this leaflet carefully before you start using 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 Zomig Nasal is and what it is used for
2. What you need to know before you use Zomig Nasal
3. How to use Zomig Nasal
4. Possible side effects
5. How to store Zomig Nasal
6. Contents of the pack and other information

1. What Zomig Nasal is and what it is used for

Zomig Nasal contains zolmitriptan and belongs to a group of medicines called triptans.

Zomig Nasal is used to treat migraine headache in adults and adolescents aged 12 years and older and cluster headache in adults.

- Headache symptoms may be caused by the widening of blood vessels in the head. Zomig Nasal is thought to reduce the widening of these blood vessels. This helps to take away the headache and other common symptoms of the attack, such as:
 - feeling or being sick (nausea or vomiting) and being sensitive to light and sound during a migraine attack.
 - watering and redness of the eye (conjunctival injection) and blocked or watering nose, on the same side as the pain during a cluster headache attack.
- Zomig Nasal works only when a headache attack has started. It will not stop you from getting an attack.

2. What you need to know before you use Zomig Nasal

Do not use Zomig Nasal:

- if you are allergic to zolmitriptan or any of the other ingredients of this medicine (listed in section 6).
- if you have high blood pressure
- if you have ever had heart problems, including a heart attack, angina (chest pain caused by exercise or effort), Prinzmetal's angina (chest pain which happens at rest) or have experienced heart related symptoms such as shortness of breath or pressure over the chest
- if you have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA)
- if you have severe kidney problems
- if you are at the same time taking some other medicines for migraine (e.g. ergotamine or ergot-type medicines like dihydroergotamine and methysergide) or other triptan medicines for migraine. See section below: 'Taking other medicines' for further information.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before using Zomig Nasal if:

- you are at risk of getting ischaemic heart disease (poor blood flow in the arteries of the heart). Your risk is greater if you smoke, have high blood pressure, high levels of cholesterol, diabetes or if anyone in your family has ischaemic heart disease.
- you have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heart beat)
- you have ever had liver problems
- you have headaches which are not like your usual migraine or cluster headache
- you are taking any other medicine for treatment of depression (see 'Taking other medicines' later in this section).

If you go into hospital tell the medical staff you are taking Zomig Nasal.

Zomig Nasal is not recommended for children aged under 12 years or adults over 65.

As with other migraine treatments, using too much Zomig Nasal can cause daily headaches or can make your migraine headaches worse. Ask your doctor if you think that this is the case for you. You may need to stop using Zomig Nasal to correct the problem.

Other medicines and Zomig Nasal

Tell your doctor or pharmacist if you are taking, have recently taken any or might take any other medicines. This includes herbal medicines and medicines you buy without prescription.

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

Medicines for migraine or cluster headache:

- If you take triptans other than Zomig Nasal, leave 24 hours before using Zomig Nasal.
- After using Zomig Nasal leave 24 hours before taking triptans other than Zomig Nasal.
- If you take medicines containing ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before using Zomig Nasal.
- After using Zomig Nasal leave 6 hours before taking ergotamine or ergot-type medicines.

Medicines for depression:

- moclobemide or fluvoxamine
- medicines called SSRIs (selective serotonin reuptake inhibitors)
- medicines called SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine, duloxetine

Serotonin syndrome is a rare, life-threatening condition that has been reported in some patients who took Zomig in combination with so called serotonergic medicines (e.g. certain medicines for the treatment of depression). Signs of serotonin syndrome may be for example, agitation, tremor, restlessness, fever, excessive sweating, twitching, muscle rigidity uncoordinated movement of limbs or eyes and uncontrollable jerking of muscles. Your doctor may advise you on this.

Other medicines:

- cimetidine (for indigestion or stomach ulcers)
- a quinolone antibiotic (such as ciprofloxacin)

If you are using herbal remedies containing St John's Wort (*Hypericum perforatum*), side effects of Zomig Nasal may be more likely to happen.

Zomig Nasal with food and drink

You can take Zomig Nasal with or without food. It does not affect the way that Zomig Nasal works.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- It is not known if using Zomig Nasal during pregnancy is harmful. Before using Zomig Nasal, tell your doctor if you are pregnant or trying to become pregnant.
- Do not breast-feed within 24 hours of using Zomig Nasal.

Driving and using machines

- During a headache attack your reactions may be slower than usual. Bear this in mind when you drive or use any tools or machines.
- Zomig Nasal is unlikely to affect driving or using tools or machines. However, it is best to wait to see how Zomig Nasal affects you before you try these activities.

3. How to use Zomig Nasal

Zomig Nasal comes in a ready-to-use spray unit. Each unit contains either 2.5 mg or 5 mg of zolmitriptan. Each unit is for single use and gives only one dose.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on your dose, which will depend on your illness.

Migraine headache

Adults and adolescents (from the age of 12 years)

The usual dose is one spray (either 2.5 mg or 5 mg) in one nostril. It does not matter which nostril you use and you can take Zomig as soon as a migraine headache starts or once a headache is underway. You may take another dose if the migraine is still present after two hours **or** if it returns within 24 hours. However, do not use more than two spray doses in one day. If you have been prescribed the 2.5 mg spray, the maximum daily dose is 5 mg. If you have been prescribed the 5 mg spray, the maximum daily dose is 10 mg.

Cluster headache

Adults

The usual dose is 5 mg or 10 mg in one nostril. You may have a blocked nostril on the same side as the headache. If so, use your nostril that is not blocked on the opposite to the side where the headache is. You should take Zomig as soon as the cluster headache attack starts. The maximum daily dose is 10 mg. Therefore, do not use more than 4 doses of Zomig Nasal 2.5 mg or 2 doses of Zomig Nasal 5 mg in any 24-hour period.

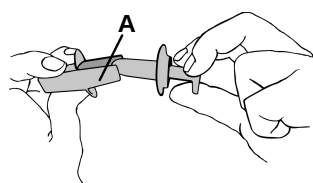
If the nasal spray did not give you enough help with your headache, tell your doctor. Your doctor may raise the dose or change your treatment.

How to use Zomig Nasal

Please read these instructions before using Zomig Nasal.

A. The Protective Cover:

- This covers the nozzle to protect it.
- Remove it before you use the nasal spray.



B. The Nozzle:

- You put this part into your nose.
- The medicine comes out of a tiny hole in the top.



C. The Finger-grip:

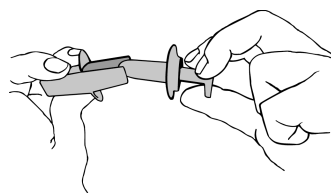
- You hold this part when you use the spray.

D. The Plunger:

- You press this part once you have put the nozzle comfortably into your nose.
- The spray contains only one dose and works only once.

Do not press the plunger until you have put the nozzle in your nostril or you will lose the dose.

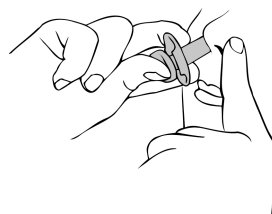
- 1
- Blow your nose gently before use.
 - Remove the protective cover.
- 1



- 2
- Hold the nasal spray gently with your fingers and thumb as shown in picture 2.
- Do not press the plunger yet!
- 2



- 3
- Block one nostril by pressing a finger on the side of your nose as shown in picture 3. (If you already have a blocked nostril as a symptom of your illness this may not be needed.)
- 3
- Put the nozzle of the nasal spray into the other unblocked nostril as far as feels comfortable.
 - Tilt your head back slightly and close your mouth as shown in picture 3.
 - Breathe in gently through your nose and at the same time press the plunger firmly with your thumb. The plunger may feel stiff and you may hear it click.
 - Keep your head slightly tilted back. Remove the nozzle from your nose.
 - Breathe gently through your mouth for 5-10 seconds. You may feel liquid inside your nose. This does not mean that the dose is being lost



or that the spray has failed. This is normal and will soon pass.

If you use more Zomig Nasal than you should

If you have taken more Zomig Nasal than prescribed by your doctor, tell your doctor or go to the nearest hospital straight away. Take the Zomig Nasal medicine with you.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of the symptoms below could be part of the migraine attack itself.

Stop taking Zomig Nasal and contact your doctor straight away if you experience any of the following side effects:

Rare side effects (may affect up to 1 in 1,000 people):

- Allergic/hypersensitivity reactions including lumpy rash (hives), swelling of the face, lips, mouth, tongue or throat; difficulty swallowing or breathing difficulties.

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

- Angina (pain in the chest, often brought on by exercise), heart attack or spasm of the blood vessels of the heart. You may notice chest pain or shortness of breath.
- Spasm of the blood vessels of the gut, which can cause damage to your gut. You may notice stomach pain or bloody diarrhoea.

Other side effects that may occur:

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

- Taste disturbance.

Common side effects (may affect up to 1 in 10 people):

- Abnormal sensations such as tingling in your fingers and toes or skin that is sensitive to touch
- Feeling sleepy, dizzy or warm
- Headache
- Uneven heart beat
- Nose bleed. Irritation in the nose. Blocked and/or runny nose (rhinitis)
- Feeling sick. Vomiting
- Stomach pain
- Dry mouth
- Muscle weakness or muscle pain
- Feeling weak
- Heaviness, tightness, pain or pressure in throat, neck, arms and legs or chest
- Difficulty in swallowing

Uncommon side effects (may affect up to 1 in 100 people):

- Very fast heart beat
- Slightly higher blood pressure
- Increase in the amount of water you pass (urine) or in how often you need to pass water

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zomig Nasal

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zomig Nasal contains

The active substance is zolmitriptan. Zomig Nasal contains either 2.5 mg or 5 mg zolmitriptan in each dose. The other ingredients are: citric acid, disodium phosphate and purified water.

What Zomig Nasal looks like and contents of the pack

- Zomig Nasal 2.5 mg/dose and 5 mg/dose nasal spray is a pre-assembled device.
- Zomig Nasal 2.5 mg/dose comes in pack sizes of 1, 2 or 6 single use nasal spray units.
- Zomig Nasal 5 mg/dose comes in pack sizes of 1, 2, 6 or 18 single use nasal spray units.
- Each nasal spray unit is ready-to-use and gives only one dose.

Not all pack sizes may be marketed.

Zomig may also be available as film-coated tablets 2.5 mg and 5 mg and orodispersible tablets 2.5 mg and 5 mg.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name of medicinal product
Austria, Italy, Spain	Zomig
Belgium, Denmark, Finland, Luxemburg, Portugal, Sweden and Norway	Zomig Nasal
Germany	AscoTop Nasal

This leaflet was last approved in

2025-05-12

[To be completed nationally]