

Zomig Nasal Spray®

Zolmitriptan 5 mg Nasal Spray Solution.

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Zomig Nasal Spray**. It does not contain all the information that is known about **Zomig Nasal Spray**.

It does not take the place of talking to your doctor or pharmacist.

Your pharmacist or doctor has weighed the risks of you taking **Zomig Nasal Spray** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

What Zomig Nasal Spray is used for

Zomig Nasal Spray contains the active ingredient zolmitriptan. It belongs to a group of medicines called serotonin agonists (triptans).

Zomig Nasal Spray is used for the acute relief of migraine attacks, with or without what is known as ~~aura~~ a forewarning of an attack. This may include visual disturbances such as brilliant flickering lights or blurring of vision; or sensory disturbances such as numbness or weakness of the limbs.

Zomig Nasal Spray is only suitable in patients who have a stable, well-established pattern of symptoms. It should not be used to prevent migraine attacks from occurring.

Migraine attacks are thought to be caused by the swelling of blood vessels in the brain. **Zomig Nasal Spray** helps to relieve the symptoms of a migraine attack by reducing the size of the blood vessels back to normal.

Zomig Nasal Spray helps to relieve other symptoms that occur together with a migraine headache, such as feeling sick and sensitivity to light and sound. **Zomig Nasal Spray** does not relieve the symptoms of other headaches that are not migraine headaches.

Zomig Nasal Spray is a pre-assembled device and comes in a pack of two available from your pharmacist. Each nasal spray device is ready-to-use and contains only one dose.

Before you use Zomig Nasal Spray

When you must not use it

Do not take Zomig Nasal Spray if you are allergic to zolmitriptan, sulphur (e.g. sulphonamides) or any ingredients listed at the end of this leaflet.

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 take Zomig Nasal Spray if you have or have ever had:

- Heart disease, or previous heart attack
- Heart problems including irregular heartbeat
- Vascular problems (including a stroke or clot)
- High blood pressure
- Angina, including Prinzmetal's angina
- Shortness of breath, pain or tightness in the chest, neck, jaw or upper arm
- Liver failure
- Severe kidney disease.

Do not take Zomig Nasal Spray if you have taken Monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression within the last 14 days. Ask your pharmacist or doctor if you are unsure as to whether or not you are taking a MAOI.

Do not take Zomig Nasal Spray if you have taken any of the following other medicines used to treat migraines in the past 24 hours:

- Other medicines belonging to the group of medicines known as the triptans or serotonin agonists (eg. sumatriptan, rizatriptan)
- Ergotamine containing medicines or derivatives of ergotamine (including methysergide containing medicines).

Do not take Zomig Nasal Spray if you are pregnant, plan to become pregnant or you are breastfeeding, without first discussing this with your doctor.

Your doctor will assess the risks and benefits of taking **Zomig Nasal Spray** if you are pregnant or breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell them before you take **Zomig Nasal Spray**.

Do not take **Zomig Nasal Spray** after the expiry date (EXP) printed on the pack. If you take it after the expiry date has passed, it may not work as well.

Do not take **Zomig Nasal Spray** if the packaging is torn or shows signs of tampering.

Before you take it

Tell your pharmacist if:

- you are over 65 or under 18 years of age. Zomig Nasal Spray is only suitable for patients between 18 and 65 years of age
- your headache has not been diagnosed by a doctor as a migraine
- you have different symptoms, or if you feel that this migraine is different or worse than your usual migraine
- you have difficulty moving one side of your body when you have a migraine+headache.

Also tell your pharmacist or doctor if you are allergic to:

- any other medicines, foods, dyes or preservatives
- medicines that contain sulphur.

you have or have had any of these medical conditions:

- Liver or kidney problems
- A stroke
- Any problems with your heart, including irregular heart beats, or if
- you have a family history of heart problems
- High blood pressure
- High cholesterol
- Angina or any other chest pain or tightness
- Shortness of breath, pain or tightness in the chest, neck, jaw or upper arm.

Taking other medicines

You must tell your doctor if you are taking any other medicines, including:

- another triptan ie sumatriptan, rizatriptan
- selective serotonin reuptake inhibitors (SSRI) or a serotonin noradrenaline reuptake inhibitor (SNRI). If you are unsure if you are or not, ask your pharmacist or doctor. These are used to treat depression
- Ergotamine, dihydroergotamine or methysergide
- Cimetidine for the treatment of stomach ulcers
- Antibiotics known as quinolones
- St Johns Wort (hypericum perforatum).

If you have not told your pharmacist or doctor about any of the above, tell them before you take

Zomig Nasal Spray.

Your pharmacist will consider if **Zomig Nasal Spray** should be used together with any of these medicines. These medicines may affect the way **Zomig Nasal Spray** works.

Effects on driving and using machinery

Be careful driving a car or operating machinery until you know how Zomig Nasal Spray affects you.

Zomig Nasal Spray can make some people feel dizzy or sleepy. Make sure you know how you react to **Zomig Nasal Spray** before you do anything that could be dangerous if you are dizzy or sleepy.

Taking Zomig Nasal Spray

Follow all directions given to you by your pharmacist carefully.

Do not remove the protective cover until immediately before use. Each nasal spray contains one dose.

How much to take

One nasal spray dose (5 mg) into one nostril.

If your migraine is still present within 24 hours or if it returns **do not take another dose**, see your pharmacist or doctor.

When to take it

It is best to take **Zomig Nasal Spray** either when your migraine begins or when other symptoms of the migraine headache begin. These symptoms may include nausea, vomiting or your eyes becoming sensitive to light. If you take **Zomig Nasal Spray** during the migraine it may still work.

Do not take **Zomig Nasal Spray** before your symptoms occur.

How to take it

The **Zomig Nasal Spray** device consists of the following parts:

A. The Protective Cap: This covers the tip to protect it. Do not remove the protective cap until just before you are ready to take your **Zomig Nasal Spray**.

B. The Tip: This is the part you put in your nostril. The medicine comes out of a tiny hole in the top.

C. The Finger-grip: This is the part you hold when you use the sprayer.

D. The Plunger: This is the part that you press when you put the tip into your nostril. This sprayer works only once.

Figure 1

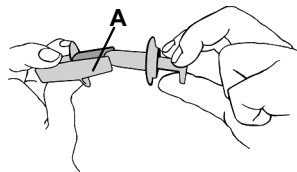


Figure 2

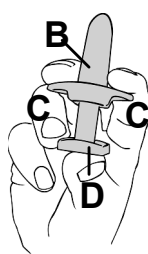
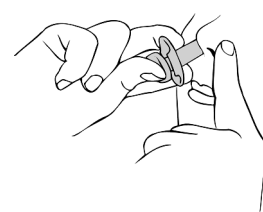


Figure 3



Steps for using Zomig Nasal Spray

Read all steps before using for the first time.

- 1) Blow your nose gently before use. Remove the protective cap (A) see Figure 1.
Hold the nasal spray device gently with your fingers and thumb as shown in Figure 2 below.
There is only one dose in the nasal sprayer.
 - **Do not try to prime the nasal sprayer or you will lose the dose.**
 - **Do not press the plunger until you have put the tip into your nostril or you will lose the dose.**
- 2) Block one nostril by pressing firmly on the side of your nose (Figure 3). Either nostril can be used.
Put the tip (B) of the sprayer device into the other nostril as far as feels comfortable and tilt your head back slightly.
- 3) Breathe in gently through your nose at the same time press the plunger (D) firmly with your thumb. The plunger may feel stiff and you may hear a click. Keep your head slightly tilted back

and remove the tip from your nose. Breathe gently through your mouth for 5-10 seconds. You may feel liquid in your nose or the back of your throat. This is normal and will soon pass.

While you are using Zomig Nasal Spray

Things you must do

Tell all doctors, dentists and pharmacists who treat you that you have recently taken **Zomig Nasal Spray**.

If you are about to be started on any new medicine, remind your pharmacist or doctor that you have recently taken **Zomig Nasal Spray**.

If you are pregnant, plan to become pregnant or are breastfeeding, tell your doctor or pharmacist.

Things you must not do

Do not give **Zomig Nasal Spray** to anyone else, even if they have the same condition as you.

Do not use **Zomig Nasal Spray** to treat any other medical complaints.

Do not use **Zomig Nasal Spray** for any other headache that is not a migraine headache. **Zomig Nasal Spray** only treats migraine headaches.

Do not take **Zomig Nasal Spray** to try and prevent a migraine attack.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Zomig Nasal Spray.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

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:

- strange taste
- blood nose
- discomfort inside nose
- dry mouth
- dizziness or feelings of weakness
- drowsiness or fatigue (tiredness)
- nausea (feeling sick) or vomiting
- stomach pain
- feelings of tingling, warmth, cold, heaviness, pressure, or pain in different parts of the body
- increased feeling or sensitivity, especially in the skin
- aching muscles not caused by exercise.

These are generally mild adverse effects and may occur in a small number of people.

Tell your doctor as soon as possible if you notice any of the following:

- changes in the speed of your heart rate (increase or decrease) or irregular heart beat
- shortness of breath or difficulty breathing
- feeling faint or fainting.

These may be serious side effects. You may require urgent medical attention. These side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- pain, heaviness, pressure or tightness in any part of the body including the chest or throat
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing
- skin rash or hives.

If you experience any of these side effects, you may have had a serious allergic reaction to **Zomig Nasal Spray**. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Zomig Nasal Spray**. Tell your pharmacist if you notice anything else that is making you feel unwell or bothering you.

Overdose

Please telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Zomig Nasal Spray, even if there are no signs of discomfort or poisoning.

Storage

Keep your **Zomig Nasal Spray** 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 your **Zomig Nasal Spray** in a cool dry place where the temperature stays below 25°C.
Do not leave **Zomig Nasal Spray** in the car on hot days.

Disposal

Ask your pharmacist what to do with **Zomig Nasal Spray** after you have used it, or you find that the expiry date has passed.

What Zomig Nasal Spray looks like

Zomig Nasal Spray is a dark blue coloured plastic sprayer device with a grey protection cap.

Ingredients:

Zomig Nasal Spray contains 5 mg of zolmitriptan.

The other ingredients are:

- citric acid
- disodium phosphate
- purified water.

Marketed by:

AstraZeneca Limited, Private Bag 92175/299, Auckland 1142. Telephone: (09) 306 5650.

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