

## **Package leaflet: Information for the user**

### **Zomig 5 mg Nasal Spray** 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 Spray is and what it is used for
2. What you need to know before you use Zomig Nasal Spray
3. How to use Zomig Nasal Spray
4. Possible side effects
5. How to store Zomig Nasal Spray
6. Contents of the pack and other information

### **1. What Zomig Nasal Spray is and what it is used for**

Zomig 5 mg Nasal Spray contains zolmitriptan and belongs to a group of medicines called triptans.

Zomig Nasal Spray is used to treat migraine headache.

- Migraine symptoms may be caused by swollen blood vessels in the head. Zomig Nasal Spray is thought to reduce the widening of these blood vessels. This helps to take away the headache and other symptoms of a migraine attack, such as feeling or being sick (nausea or vomiting) and being sensitive to light and sound.
- Zomig Nasal Spray works only when a migraine attack has started. It will not stop you from getting an attack.

### **2. What you need to know before you use Zomig Nasal Spray**

#### **Do not use Zomig Nasal Spray:**

- 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 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: '**Other medicines and Zomig Nasal Spray**' for further information.

Do not use Zomig Nasal Spray if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Zomig Nasal Spray.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Zomig Nasal Spray:

- 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.
- If you have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heart beat).
- If you have ever had liver problems.
- If you have headaches which are not like your usual migraine headache.
- If you are taking any medicine for treatment of depression (see section below: **‘Other medicines and Zomig Nasal Spray’** for further information).

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

Zomig Nasal Spray is not recommended for people aged over 65.

### **Children and adolescents**

Zomig Nasal Spray is not recommended for children and adolescents aged under 18 years.

As with other migraine treatments, using too much Zomig Nasal Spray 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 Spray to correct the problem.

### **Other medicines and Zomig Nasal Spray**

Tell your doctor or pharmacist if you are taking, have recently taken 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:*

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

#### *Medicines for depression:*

- Mono-Amine Oxidase Inhibitors, also known as MAOIs (such as moclobemide).
- SSRIs (selective serotonin reuptake inhibitors) such as fluoxetine, paroxetine, fluvoxamine or sertraline.
- SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine or 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, restlessness, fever, excessive sweating, tremor, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, twitching and muscle rigidity. Your doctor may advise you on this.

*Other medicines:*

- Cimetidine (for indigestion or stomach ulcers).
- A quinolone antibiotic (such as ciprofloxacin).

You should not take the herbal remedy St. John's wort (*Hypericum perforatum*) at the same time as this medicine. If you already take a St. John's wort preparation, stop taking the St. John's wort and mention this to your doctor at your next visit.

**Zomig Nasal Spray with food and drink**

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

**Pregnancy, breast-feeding and fertility**

It is not known if using Zomig Nasal Spray during pregnancy is harmful. 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 using this medicine.

**Driving and using machines**

During a migraine attack your reactions may be slower than usual. Bear this in mind when you drive or use any tools or machines.

Zomig Nasal Spray is unlikely to affect driving or using tools or machines. However, it is best to wait to see how Zomig Nasal Spray affects you before you try these activities.

**3. How to use Zomig Nasal Spray**

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

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You can use Zomig Nasal Spray as soon as a migraine headache starts. You can also use it once an attack is underway.

- The recommended dose is one spray (5 mg) in one nostril. It does not matter which nostril you use.
- You can use another spray if the migraine is still present after two hours or if it returns within 24 hours.

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

Do not use more than the dose prescribed for you.

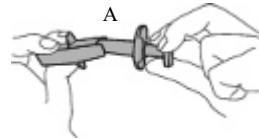
- Do not use more than two spray doses in one day.
- The maximum daily dose is 10 mg.

**How to use Zomig Nasal**

Please read these instructions before using Zomig Nasal Spray.

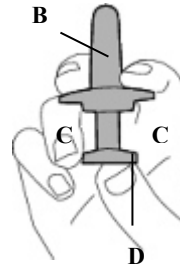
**A. The Protective Cover:**

- 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.

1



- Remove the protective cover.

- 2 • Hold the nasal spray gently with your fingers and thumb as shown in picture 2.

2



**Do not press the plunger yet!**

- 3 • Block one nostril by pressing a finger on the side of your nose as shown in picture 3.

3



- Put the nozzle of the nasal spray into the other 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 Spray than you should**

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

### **If you forget to take Zomig**

- Do not take a double dose to make up for a forgotten dose.

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. Some of the symptoms below could be part of the migraine attack itself.

**Stop using Zomig Nasal Spray and contact your doctor straight away if you notice any of the following:**

### **Rare (may affect up to 1 in 1,000 people)**

- Allergic reactions including itchy rash (urticaria) and swelling of the face, lips, mouth, tongue and throat.

### **Very rare (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. The signs include chest pain and shortness of breath.
- Spasm of the blood vessels of the gut, which can cause damage to your gut. The signs include stomach pain or bloody diarrhoea.
- Bleeding in the brain (cerebral bleeding) or stroke.

Other possible side effects include:

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

This is usually mild and goes away after a short time.

- Taste disturbance.

### **Common (may affect up to 1 in 10 people):**

These are usually mild and go away after a short time.

- 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 or the nose being more sensitive than usual.
- Feeling sick (nausea) or being sick (vomiting).
- Stomach pain.
- Dry mouth.
- Muscle weakness or muscle pain.
- Feeling weak.
- Heaviness, tightness, pain or pressure in the throat, neck, arms and legs or chest.
- Problems swallowing.

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

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

Do not be concerned by this list of possible side effects. You may not get any of them.

**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 Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.
- Keep your medicine in the container it came in.
- 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 5 mg Nasal Spray contains**

The active ingredient is zolmitriptan. Each dose contains 5 mg zolmitriptan. The other ingredients are: citric acid, disodium phosphate and purified water.

**What Zomig 5 mg Nasal Spray looks like and contents of the pack**

- Zomig 5 mg Nasal Spray is a pre-assembled device.
- Zomig 5 mg Nasal Spray comes in pack containing 1, 2 or 6 single use nasal spray units. Not all pack sizes may be marketed.
- Each nasal spray unit is ready-to-use and gives only one dose.

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

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation for Zomig 5 mg Nasal Spray is held by Grünenthal Ltd, Regus Lakeside House, 1 Furzeground Way, Stockley Park East, Uxbridge, Middlesex, UB11 1BD, UK.

Zomig 5 mg Nasal Spray is manufactured by Grünenthal GmbH, Zieglerstraße 6, 52078 Aachen, Germany.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

**Product name**            **Zomig 5 mg Nasal Spray**

**Reference number**    **PL 21727/0085**

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was last revised in March 2020**