

IMIGRAN Nasal Spray Patient Information Leaflet

SCHEDULING STATUS:

S4

IMIGRAN 20 mg Nasal Spray

Sumatriptan 20 mg per spray

Read all this leaflet carefully before you start using IMIGRAN Nasal Spray.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- IMIGRAN Nasal Spray has been prescribed for you personally and you should not share your medicines with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What IMIGRAN Nasal spray is and what it is used for:

IMIGRAN Nasal Spray contains a single dose of sumatriptan, which belongs to a group of medicines called triptan.

IMIGRAN Nasal Spray is used to treat migraines.

2. What you need to know before you use IMIGRAN Nasal spray:

Do not use IMIGRAN Nasal Spray:

- if you are allergic (hypersensitive) to sumatriptan or any of the other ingredients in IMIGRAN Nasal Spray. For list of ingredients, see section 6
- if you have a heart problem such as heart failure or chest pains (angina), or have already had a heart attack
- if you have circulation problems in your legs that cause cramp-like pains when you walk (peripheral vascular disease)
- if you have had a stroke or a mini stroke (also called a transient ischaemic attack or TIA)
- if you have liver disease, check with your doctor. If your liver problems are severe then IMIGRAN is not suitable for you
- with other migraine medicines, including those which contain ergotamine, or similar medicines such as methysergide
- with anti-depressants called MAOIs (monoamine oxidase inhibitors), or if you have taken these medicines in the last two weeks.

If you think any of these apply to you, **don't use IMIGRAN Nasal Spray** until you have checked with your doctor.

Warnings and precautions:

Take special care with IMIGRAN Nasal spray:

Your doctor needs to know before you use IMIGRAN Nasal Spray:

- if you have **extra risk factors for heart disease**:
 - if you are a man over 40
 - if you are a woman who has been through the menopause
 - if you smoke or are overweight
 - if you have diabetes or high cholesterol
 - if you have a strong family history of heart disease

If any of the points in the list applies to you, it could mean you have a greater risk of developing heart disease – so please tell your doctor so that your heart function can be checked before IMIGRAN Nasal Spray is prescribed for you.

In some cases, people have developed serious heart conditions after using IMIGRAN Nasal Spray, even though they had no signs of heart disease before.

If any of the following applies to you, please tell your doctor before you start using IMIGRAN Nasal Spray:

- if you have had high blood pressure
- if you have kidney disease or mild to moderate liver disease
- if you have a history of seizures (fits), or if you have other conditions which might make it more likely that you'll have a fit – e.g. a head injury or alcoholism
- if you are allergic to antibiotics called sulphonamides, you may also be allergic to IMIGRAN nasal Spray
- if you are over 65 years old or under the age of 18 years.

While you are using IMIGRAN, your doctor needs to know: If you feel pain or tightness in your chest after you use IMIGRAN Nasal Spray. These effects may be intense, but they usually pass quickly. If they don't pass quickly, or if they become severe, get medical help immediately.

If you use IMIGRAN Nasal Spray frequently: Using IMIGRAN Nasal Spray too often may make your headaches worse. Tell your doctor if this applies to you. You may need to stop using IMIGRAN Nasal Spray.

Other medicines and IMIGRAN Nasal Spray:

Always tell your health provider if you are taking any other medicines. (This includes complementary or traditional medicines.)

Some medicines must not be taken with IMIGRAN Nasal Spray. These include:

- other medicines used to treat migraines, e.g. ergotamine and methysergide
- antidepressants called monoamine oxidase inhibitors (MAOs), or if you have taken these medicines in the last two weeks.

Some medicines may cause adverse effects if they are taken with IMIGRAN Nasal spray. These include:

- Lithium used to treat depression. Using IMIGRAN Nasal Spray with lithium may cause confusion, weakness and/or lack of co-ordination (*serotonin syndrome*).
- SSRIs (*Selective Serotonin Re-uptake Inhibitors*) or SNRIs (*serotonin-noradrenaline re-uptake inhibitors*) used to treat depression. Using IMIGRAN Nasal Spray with these medicines can cause confusion, weakness and/or lack of co-ordination (*serotonin syndrome*). **Contact your doctor immediately** if you get any of these symptoms.

- Amphetamines, used to treat hyperactivity disorders (ADHD) may also cause the serotonin syndrome.
- Fentanyl, pethidine and tramadol, used to treat pain may also cause the serotonin syndrome.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The ingredients in IMIGRAN Nasal Spray can pass into breast milk. Don't breastfeed your baby for 12 hours after using IMIGRAN Nasal Spray. If you express any breast milk during this time, discard the milk and don't give it to your baby.

Driving and using machines:

The symptoms of migraine and IMIGRAN Nasal Spray can make you drowsy. Do not drive or operate machinery, unless you are feeling well.

3. How to use IMIGRAN Nasal Spray:

Do not share medicines prescribed for you with any other person.

Always use IMIGRAN Nasal Spray exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose for adults aged 18 to 65 years, is one 20 mg spray into just one nostril.

Use IMIGRAN Nasal Spray as soon as your migraine begins. IMIGRAN Nasal Spray can also be taken at any time after the headache has started.

Do not use IMIGRAN nasal spray to try to prevent an attack.

If your symptoms start to come back, **you may take a second IMIGRAN spray** no sooner than **two hours** after the first spray.

Do not use more than two sprays in 24 hours.

If the first spray has no effect, don't use a second spray or any other IMIGRAN preparation for the same attack. If IMIGRAN doesn't give you any relief, ask your doctor or pharmacist for advice.

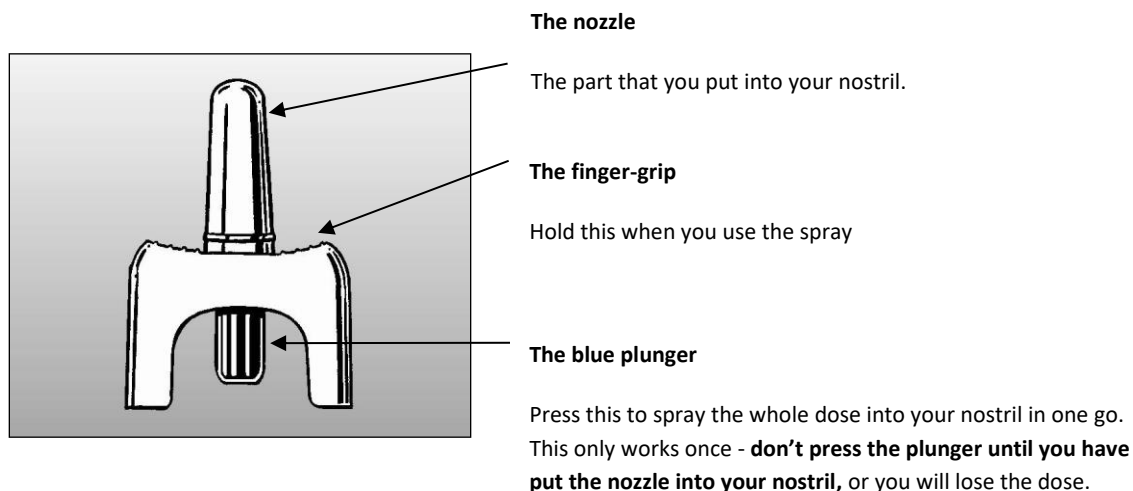
How to use:

Don't open a blister until you are ready to use a spray. Each spray is sealed in a blister to keep it clean and safe. If you carry a spray without a blister, or in an open blister, it may not work properly when you need it.

Each spray contains just one dose of IMIGRAN Nasal Spray.

Don't press the plunger too soon or you will lose the dose.

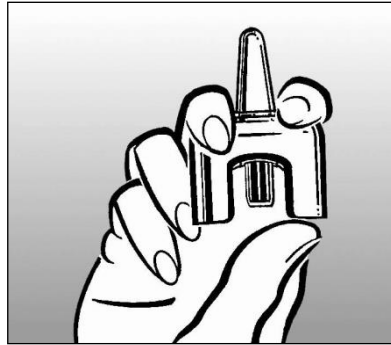
IMIGRAN nasal spray has three parts:



How to use the nasal spray:

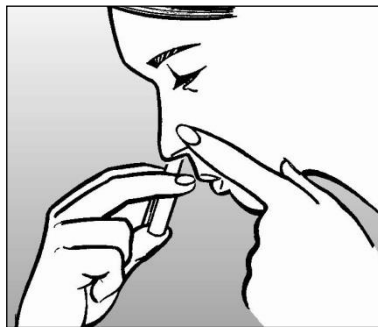
1. **Remove the nasal spray** from the blister packaging just before you want to use it.
2. Get into a comfortable position. You may prefer to sit down.

3. **Blow your nose** if it feels blocked, or if you have a cold.
4. **Hold the nasal spray** gently with your fingers and thumb as shown in picture A. **Don't press the blue plunger yet.**



Picture A

5. **Block one nostril** by pressing a finger firmly on the side of your nose. It doesn't matter which nostril you choose.



Picture B

6. **Put the nozzle of the nasal spray into the other nostril**, as far as feels comfortable – about 1cm or ½ inch (picture B)

Breathe out gently through your mouth.

Hold your head upright and close your mouth.



Picture C

7. Start to breathe in gently through your nose.

As you breathe in:

Press the blue plunger firmly with your thumb.

The plunger may feel a bit stiff, and you may feel it click. Keep breathing in while spraying (picture C).

8. Remove the spray and remove your finger from the side of your nose.

Keep your head upright for 10-20 seconds, breathing gently in through your nose and out through your mouth. This helps the medicine stay in your nose.

Your nose may feel wet inside and you may notice a slight taste after using the spray – this is normal and will soon pass.

9. Your nasal spray is now empty. Throw it away safely and hygienically.

If you use more IMIGRAN Nasal Spray than you should:

Using too much IMIGRAN Nasal Spray could make you ill. In the event of overdosage, consult your doctor or pharmacist. If neither available, contact the nearest hospital or poison centre. If possible, show them the IMIGRAN Nasal Spray pack.

4. Possible side effects:

IMIGRAN Nasal spray can have side effects.

Not all the side effects reported for IMIGRAN Nasal Spray are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using IMIGRAN Nasal Spray, please consult your healthcare provider for advice.

Allergic reactions:

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- raised and itchy rash (*hives*)
- swelling sometimes of the face or mouth (*angioedema*) causing difficulty in breathing
- collapse.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to IMIGRAN Nasal Spray. You may need urgent medical attention or hospitalisation. Do not use anymore IMIGRAN Nasal Spray.

Frequent side effects include:

- feeling dizzy, feeling tired or drowsy, unusual sensations including numbness, tingling and feeling hot or cold
- temporary increase in blood pressure, getting hot flushes
- feeling sick (nausea) or being sick (vomiting), although this may be due to the migraine itself
- pain, heaviness or pressure in any part of the body including the chest and throat
- shortness of breath
- irritation or burning sensation in your nose or throat, nosebleed
- feeling weak.

Other side effects include:

- allergic reaction
- seizures (fits), tremors, muscle spasm, neck stiffness
- visual disturbances such as flickering, reduced vision, double vision, loss of vision, and in

some cases even permanent defects (although these may be due to the migraine attack itself)

- heart problems where your heartbeat may go faster (*tachycardia*), slower (*bradycardia*) or change rhythm (*cardiac dysrhythmias*) or heart attack
- feeling faint (blood pressure may go down)
- pale, blue-tinged skin and/or pain in your fingers, toes, ears, nose or jaw in response to cold or stress (*Raynaud's phenomenon*)
- pain in the lower left side of the stomach and bloody diarrhoea (*ischaemic colitis*).

If you have a blood test to check how your liver is functioning and you have taken IMIGRAN Nasal Spray, tell your doctor as using IMIGRAN Nasal Spray may affect the results.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of IMIGRAN Nasal Spray.

5. How to store IMIGRAN Nasal Spray:

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep the nasal spray in its sealed blister in the carton to protect it from light.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What IMIGRAN Nasal Spray contains:

The active substance is sumatriptan.

A unit dose device for intranasal administration. The device contains 20 mg of sumatriptan in an aqueous buffered solution.

The other ingredients are potassium dihydrogen phosphate, dibasic sodium phosphate anhydrous, sulphuric acid, sodium hydroxide and purified water.

What IMIGRAN Nasal Spray looks like and contents of the pack:

A clear, pale yellow to dark yellow liquid.

The nasal spray comprises a vial made of Ph.Eur. Type 1 glass sealed with a rubber stopper, fitted into a cup held with the actuation device. IMIGRAN 20 mg nasal spray are individually blister packed (a clear polymer laminate and paper lidding) and then cartoned in packs of one or two.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

Registration number:

31/7.3/0197

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