

IMIGRAN® Nasal Spray

IMIGRAN® S Nasal Spray

(Sumatriptan)

Consumer Medicine Information

What is in this leaflet?

Unless explained differently, the information for "Imigran nasal spray" in this leaflet applies to both Imigran S nasal spray 10 mg and Imigran nasal spray 20 mg (refer to the "Product description" section near the end of the leaflet for a description of these two products).

Please read this leaflet carefully before you start using Imigran nasal spray.

This leaflet answers some common questions about Imigran nasal spray. It does not contain all of the available information.

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

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking Imigran nasal spray against the risks this medicine could have for you.

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

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

What is Imigran nasal spray used for?

Imigran nasal spray contains the active ingredient sumatriptan. This medicine belongs to a group of drugs called serotonin agonists.

Imigran nasal spray is used to relieve a migraine attack. It should not be used to prevent migraine attacks from occurring. Imigran nasal spray may be used for migraine headaches with or without what is known as 'aura'.

It is thought that migraine headache is due to widening of certain blood vessels in the head. Imigran nasal spray works by making those vessels normal again and eases the symptoms of migraine.

Your Imigran nasal spray does not work in other types of headache which are not a migraine.

Imigran nasal spray is not addictive.

Before you use Imigran nasal spray

Do not use if:

You must not use Imigran nasal spray if:

- **you have ever had an allergic reaction to sumatriptan (see "Side Effects") or any of the ingredients listed toward the end of this leaflet. (See "Ingredients").**

- **you have or have had:**
 - heart disease or heart attack.
 - shortness of breath, pain or tightness in the chest, jaw or upper arm.
 - peripheral vascular disease (pain in the back of the legs) or are prone to cold, tingling or numb hands and feet.
 - Prinzmetal's angina (an uncommon form of angina where pain is experienced at rest rather than during activity).
 - angina.
 - high blood pressure.
 - stroke.
 - severe liver disease.
- **you have taken any of these medicines in the last 24 hours:**
 - Ergotamine (eg Cafergot)
 - Dihydroergotamine (eg Dihydergot)
 - Methysergide (eg Deseril)
 - Naratriptan (eg Naramig)
 - Zolmitriptan (eg Zomig).
- **you have taken any of these medicines in the last two weeks:**
 - Monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression.
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering.**

Tell your doctor if:

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines, including any that contain sulphur (eg sulphonamide antibiotics).**

- you are taking medicines containing SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin-Noradrenaline Reuptake Inhibitors) used to treat depression.
- **you are taking or have taken any other medicines in the last two weeks, including medicines you buy without a prescription, particularly herbal preparations containing St John's Wort and medicines prescribed for depression.**
- **you are breastfeeding, pregnant or trying to become pregnant.**
- **you have or have had medical conditions like:**
 - liver or kidney problems.
 - heart problems. Risk factors including high blood pressure, even if it is under control, high blood cholesterol levels, a family history of heart problems, obesity, diabetes, you are male and over 40 years of age, you are female and have undergone menopause or you smoke.
 - epilepsy, seizures, or fits or been told that you are prone to this problem.
 - stroke.
 - asthma, hayfever or have experienced sensitivity to other medicines which you have used nasally.
 - allergy to latex or rubber.

How do I use Imigran nasal spray?

See the patient instruction leaflet inside the pack for information on how to use your Imigran nasal spray. If there is something you do not understand, ask your doctor or pharmacist.

How much to use

Adults and Adolescents (12 years and over):

The dose is one nasal spray of 10 mg or 20 mg. Your doctor will tell you which dose is right for you.

If the first Imigran nasal spray helps your migraine, but the migraine comes back later, you may use another Imigran nasal spray. You must wait at least two hours between using the first and second Imigran nasal spray. Do not use more than 40 mg of Imigran nasal spray in any twenty-four hours. Four 10 mg strength or two 20 mg strength nasal sprays contain 40 mg.

Do not use a second Imigran nasal spray, or any other form of Imigran, if the first nasal spray has not provided any relief from your symptoms. You may take your usual headache relief medication provided it does not contain ergotamine or methysergide. If you are not sure what to do, ask your doctor or pharmacist.

If your migraine is not relieved by Imigran, you may use Imigran nasal spray on another occasion to treat another migraine attack. Provided there are no side effects, you can use Imigran nasal spray to treat at least three separate migraine attacks before you and your doctor decide this medicine is ineffective for you.

When to use it

It is best to use your Imigran nasal spray:

- a) when the migraine headache begins; or
- b) when other symptoms of the migraine begin, such as nausea (feeling sick), vomiting or your eyes becoming sensitive to light.

If you use your Imigran nasal spray later during the migraine attack it will still work for you. Do not use your Imigran nasal spray before the above symptoms occur.

What do I do if I use too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think you or anyone else may have used too many Imigran nasal sprays, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

If you accidentally spray Imigran in your eye(s) wash them with plenty of water. If there is any irritation seek medical help.

While you are using Imigran nasal spray

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

As with many other medicines, Imigran nasal spray may cause drowsiness in some people.

Be careful driving or operating machinery until you know how Imigran nasal spray affects you.

If you use Imigran nasal spray too often, it may make your headache worse. If this happens, your doctor may tell you to stop taking Imigran nasal spray.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to using Imigran nasal spray, even if the problem is not listed below.

Like other medicines, Imigran nasal spray can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Tell your doctor if you experience any of the following after using Imigran nasal spray:

- pain, tingling, heat or flushing in any part of the body.
- feeling of sleepiness, dizziness or tiredness.
- nausea (feeling sick) or vomiting.
- a change in blood pressure.
- feeling of faintness.
- irritation or burning in the nose or throat.
- nasal bleeding.
- problems with your eyesight.
- pain in the lower tummy and bloody diarrhoea (ischaemic colitis).
- shaking or tremors.
- uncontrolled movements.
- shortness of breath.

Tell your doctor immediately, or seek urgent medical attention, and do not take any more Imigran nasal spray if you:

- feel heaviness, pressure or tightness in any part of the body including the chest or throat.
- feel irregular heart beats.
- have a fit or convulsion.
- have wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting. These could be a symptom of an allergic reaction.

- have persistent purple discolouration and/or pain in the fingers, toes, ears, nose or jaw in response to cold.

These side effects are likely to be serious. Stop using Imigran nasal spray and seek medical attention straight away.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store Imigran nasal spray?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep Imigran nasal spray in a cool, dry place where it stays below 30°C and protect from light.

Do not leave it in a car, on a window sill or in a bathroom.

Keep Imigran nasal spray in its pack until it is time to use it.

Return any unused or expired medicine to your pharmacist.

Product description

What Imigran nasal spray looks like

Imigran nasal spray comes in two strengths:

- Imigran S nasal spray 10 mg - This contains a single 10 mg dose in a glass vial.
- Imigran nasal spray 20 mg - This contains a single 20 mg dose in a glass vial.

Tell your doctor if you have an allergy to latex or rubber as each vial is sealed with a rubber stopper.

Imigran nasal spray is packed in a box containing two nasal sprays.

Ingredients

Imigran nasal spray contains the active ingredient sumatriptan.

Imigran nasal spray also contains monobasic potassium phosphate, dibasic anhydrous sodium phosphate, sulfuric acid, sodium hydroxide and purified water.

Supplier

Your Imigran nasal spray is supplied by:

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos Street
St Leonards, NSW 2065
Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

This leaflet was prepared on 27 October 2009.

The information provided applies only to: Imigran® S nasal spray 10 mg and Imigran® nasal spray 20 mg.

® Imigran is a registered trade mark of Aspen Global Incorporated.

Imigran® S Nasal spray Sumatriptan 10 mg: AUST R 61565.

Imigran® Nasal spray Sumatriptan 20 mg: AUST R 61566.

© 2003 Aspen Global Incorporated.

Version 2.0