

IMIGRAN[®] Mk II Injection

(Sumatriptan succinate)

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start using Imigran Mk II injection.

This leaflet answers some common questions about Imigran Mk II injection. 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 using Imigran Mk II injection 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 Mk II injection used for?

Imigran Mk II injection contains the active ingredient sumatriptan succinate. This medicine belongs to a group of drugs called serotonin agonists.

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

It is thought that migraine headaches and cluster headaches are due to widening of certain blood vessels in the head. Imigran Mk II injection works by making those vessels normal again and eases the symptoms of migraine and cluster headaches.

Your Imigran Mk II injection does not work in other types of headache which are not a migraine or a cluster headache.

Imigran Mk II injection is not addictive.

Before you use Imigran Mk II injection

Do not use if:

You must not use Imigran Mk II injection if:

- **you have ever had an allergic reaction to sumatriptan succinate (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. Dihyergot)
 - 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.
 - SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin-Noradrenaline Reuptake Inhibitors) used to treat 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 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

How do I use Imigran Mk II injection?

The first time you ever have an Imigran Mk II injection it must be under the supervision of a doctor. After this you must use the injection as your doctor has instructed.

See the patient instruction leaflet inside the pack for information on how to load the Autoinjector with the syringe and how to discard the empty syringes. If there is something you do not understand, ask your doctor or pharmacist.

How much to use

For adults aged 18 to 65, the dose is one injection of 6 mg, just under the skin, on the outside of the thigh.

If the first Imigran Mk II injection helps your migraine or cluster headache, but the headache/migraine comes back later, you may use another Imigran Mk II injection. You must wait at least one hour between using the first and second Imigran

Mk II injection. Do not use more than 2 injections (2 x 6 mg) in any twenty-four hours.

Do not use a second injection, or any other form of Imigran, if the first injection 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 or cluster headache is not relieved by Imigran, you may use Imigran Mk II injection on another occasion to treat another attack. Provided there are no side effects, you can use Imigran Mk II injection to treat at least three separate migraine or cluster headache attacks before you and your doctor decide this medicine is ineffective for you.

How to use it

Imigran Mk II injection should be injected just under the skin on the outside of the thigh using the autoinjector (see the patient instruction leaflet inside the pack).

When to use it

It is best to use your Imigran Mk II injection -

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

If you use Imigran Mk II injection later during the attack it will still work for you. Do not use your Imigran Mk II injection before the above symptoms occur.

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

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if

you think you or anyone else may have used too many Imigran Mk II injections, 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.

While you are using Imigran Mk II injection

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 Mk II injection may cause drowsiness in some people.

Be careful driving or operating machinery until you know how Imigran Mk II injection affects you.

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

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 Mk II injection, even if the problem is not listed below.

Like other medicines, Imigran Mk II injection 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.

A common side-effect with Imigran Mk II injection is temporary pain at the site of injection.

Tell your doctor if you experience any of the following after using Imigran Mk II injection:

- 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.
- 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 use any more Imigran Mk II injection 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 Mk II injection 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 Mk II injection?

Keep your autoinjector and Imigran Mk II injections where children cannot reach them, such as in a locked cupboard.

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

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

Keep Imigran Mk II injection in its pack until time to use.

Return any unused or expired medicine to your pharmacist.

Product description

What Imigran Mk II injection looks like

Imigran Mk II injection is a pre-filled 0.5 mL volume syringe containing 6 mg sumatriptan (as succinate), in solution.

Each syringe is designed to be loaded into and used with the autoinjector device.

Imigran Mk II injection is packed in a box containing two syringe cartridges. Each syringe contains one dose of Imigran.

Imigran Mk II injection is also available as an Autoinjector Kit.

Ingredients

Imigran Mk II injection contains the active ingredient sumatriptan succinate.

Imigran Mk II injection also contains sodium chloride and water for injection.

Supplier

Your Imigran Mk II injection is supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway

Boronia

Victoria, 3155

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 20 October 2009.

The information provided applies only to: Imigran[®] Mk II injection.

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Imigran[®] Mk II Injection
Sumatriptan (as succinate) 6 mg/
0.5 mL: AUST R 44465.

Imigran Mk II Injection Autoinjector
Kit Sumatriptan (as succinate) 6 mg/
0.5 mL: AUST R 44466.

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