IMIGRAN MIGRAINE®

(Sumatriptan succinate)

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using IMIGRAN MIGRAINE?

IMIGRAN MIGRAINE contains the active ingredient Sumatriptan. IMIGRAN MIGRAINE is used to relieve a migraine attack in patients who have a stable, well-established pattern of symptoms. IMIGRAN MIGRAINE may be used for migraine headaches with or without what is known as 'aura'. For more information, see Section 1. Why am I using IMIGRAN MIGRAINE? in the full CMI.

2. What should I know before I use IMIGRAN MIGRAINE?

Do not use if you have ever had an allergic reaction to IMIGRAN MIGRAINE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use IMIGRAN MIGRAINE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IMIGRAN MIGRAINE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use IMIGRAN MIGRAINE?

The recommended dose for adults aged 18 to 65 years is 50 mg (one tablet). If the first tablet helps your migraine, but the migraine comes back later, you may take another 50 mg tablet. Wait at least two hours after the first tablet was taken. Do not take more than 100 mg (2 tablets) in any 24-hour period.

Swallow IMIGRAN MIGRAINE whole with a drink of water. Do NOT crush or chew tablet as it has a bitter taste.

More instructions can be found in Section 4. How do I use IMIGRAN MIGRAINE? in the full CMI.

5. What should I know while using IMIGRAN MIGRAINE?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using IMIGRAN MIGRAINE. Tell your doctor if, for any reason you have not taken your medicine exactly as directed.
Things you should not do	Do not give this medication to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	Be careful driving or operating machinery until you know how IMIGRAN MIGRAINE tablets affect you. IMIGRAN MIGRAINE may cause drowsiness in some people.
Looking after your medicine	Keep this medicine where children cannot reach it, such as in a locked cupboard. Keep IMIGRAN MIGRAINE tablets in the blister pack in a cool, dry place where the temperature stays below 30°C. Keep IMIGRAN MIGRAINE tablets in their pack until time to take them. Do not leave them in a car, on a window sill or in a bathroom.

For more information, see Section 5. What should I know while using IMIGRAN MIGRAINE? in the full CMI.

6. Are there any side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking IMIGRAN MIGRAINE tablets. Some mild side effects include 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, problem with your eyesight and pain in the lower tummy and bloody diarrhea (ischemic colitis), shaking or tremors, uncontrolled movements, shortness of breath. Some serious side effects which may require medical attention include feel irregular heartbeats, suffer from a fit or convulsion, have wheezing or swelling of the lips/mouth, difficulty in breathing, hay fever,

lumpy rash ("hives") or fainting, feel heaviness, pressure or tightness in any part of the body including the chest or throat and have persistent purple discoloration and/or pain in the fingers, toes, ears, nose or jaw in response to cold.			
For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full C			
MICDAN MICDAINE tablete (Sumetrinten sussineta)			

IMIGRAN MIGRAINE

Active ingredient: Sumatriptan succinate

Consumer Medicine Information (CMI)

This leaflet provides important information about using IMIGRAN MIGRAINE. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using IMIGRAN MIGRAINE.

Where to find information in this leaflet:

- 1. Why am I using IMIGRAN MIGRAINE?
- 2. What should I know before I use IMIGRAN MIGRAINE?
- 3. What if I am taking other medicines?
- 4. How do I use IMIGRAN MIGRAINE?
- 5. What should I know while using IMIGRAN MIGRAINE?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using IMIGRAN MIGRAINE?

IMIGRAN MIGRAINE contains the active ingredient sumatriptan succinate. Migraine headache is due to widening of certain blood vessels in the head. IMIGRAN MIGRAINE works by making those vessels normal again and eases the symptoms of migraine.

IMIGRAN MIGRAINE is used to relieve a migraine attack in patients who have a stable, well-established pattern of symptoms.

They should not be used to prevent migraine attacks from occurring.

IMIGRAN MIGRAINE does not work in other types of headache which are not a migraine.

2.What should I know before I use Imigran Migraine

Warnings

Do not use IMIGRAN MIGRAINE if:

you are allergic to sumatriptan succinate, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- You have had heart disease or heart attack.
- Shortness of breath, pain or tightness in chest, jawor upper arm.
- Peripheral vascular disease (pain in the back of the legs) or are prone to cold, tingling or numb hands and feet.
- Prinzmental's angina (an uncommon form of angina where pain is experienced at rest rather than during activity).

- Angina.
- High blood pressure.
- Severe liver disease.
- If you have taken any of the following medication in the last 24 hours: ergotamine (eg cafergot), Dihydroergotamine (eg Dihydergot), Methsergide (eg Deseril), naratriptan (eg Naramig) and Zolmitriptan (eg Zomig).
- If you have taken any of the following medicines in the last two weeks: Monoamine oxidase inhibitors (MAOIs), a type of medication 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.

Check with your doctor if you:

- Are allergic to foods, dyes, preservatives or any other medicines, including any that contain sulfur (eg sulphonamide antibiotics).
- Are allergic to lactose
- Are taking or have taken 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.
- Are breastfeeding, pregnant or trying to become pregnant.
- If you have medical conditions such as, 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 a male and over 40 years of age, you are female and have undergone menopause or you smoke.
- If you suffer from epilepsy, seizures, or fits or been told that you are prone to this problem.
- Have had a stroke.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with IMIGRAN MIGRAINE and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IMIGRAN MIGRAINE.

Some medicines may interfere with IMIGRAN MIGRAINE and affect how it works

4. How do I use IMIGRAN MIGRAINE?

How much to take / use

The recommended dose for adults aged 18 to 65 years is 50 mg (one tablet). If the first tablet helps your migraine, but the migraine comes back later, you may take another 50 mg tablet. Wait at least two hours after the first tablet was taken. Do not take more than 100 mg (2 tablets) in any 24-hour period.

Do NOT take more IMIGRAN MIGRAINE tablets, or any other form of IMIGRAN MIGRAINE, if the first dose 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 MIGRAINE, you may use IMIGRAN MIGRAINE tablets on another occasion to treat another migraine attack.

When to take / use IMIGRAN MIGRAINE

It is best to take IMIGRAN MIGRAINE tablets when the migraine headache begins; or

When other symptoms of the migraine begin, such as nausea (feeling sick), vomiting or your eyes becoming sensitive to light.

If you take your tablet later during the migraine attack it will still work for you. DO NOT take your IMIGRAN MIGRAINE tablet before the above symptoms occur.

If you use too much IMIGRAN MIGRAINE

If you think that you have used too much IMIGRAN MIGRAINE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26),
- or contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using IMIGRAN MIGRAINE?

Things you should do

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

Otherwise, your doctoror pharmacist may think that is not working and change your treatment unnecessarily.

Call your doctor straight away 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 symptoms of allergic 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 taking IMIGRAN MIGRAINE tablets and seek medical attention straight away.

Remind any doctor, dentist or pharmacist you visit that you are using IMIGRAN MIGRAINE

Things you should not do

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

Driving or using machines

IMIGRAN MIGRAINE tablets may cause drowsiness in some people.

Be careful before you drive or use any machines or tools until you know how IMIGRAN MIGRAINE affects you.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep IMIGRAN MIGRAINE tablets in the blister pack in a cool, dry place, where it stays below 30°C; for example, do not store it:

in the bathroom or near a sink, or in the car or on window sills.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
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. Hay fever Shaking of tremors. Uncontrolled movements. Shortness of breath.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Feeling heaviness, pressure or tightness in any parts of the body including the chest or throat. Feel irregular heart beats Have a fit of convulsion. Have wheezing, swelling of the lips/mouth. Difficulty in breathing. Problems with your eyesight. Pain in the lower tummy and bloody diarrhea (ischemic colitis). Lumpy rash ("hives") Fainting Persistent purple discolouration and/or pain in the fingers, toes, ears, nose or jaw in response to cold.	Call your doctor straight away, or; go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What IMIGRAN MIGRAINE tablets contain

Sumatriptan succinate
Lactose
Microcrystalline cellulose
Croscarmellose sodium
Magnesium stearate
Lactose

IMIGRAN MIGRAINE tablets contain lactose

IMIGRAN MIGRAINE tablets 50mg are coated with Opadry YS-1-1441-G

Do not take this medicine if you are allergic to any of these ingredients.

What IMIGRAN MIGRAINE looks like

IMIGRAN MIGRAINE 50mg tablet are pink, film-coated, capsule shaped bivconvex tablets, engraved '50' on one face and plain on the other.

A box contains 2 tablets.

The tablets have a film coating to protect the tablet, and this gives the colour.

Australia Registration Number for IMIGRAN MIGRAINE 50mg tablets: AUST R 409791

Who distributes IMIGRAN MIGRAINE

Your IMIGRAN MIGRAINE tablets are supplied by: Aspen Pharmacare Pty Ltd 34-36 Chandos Street St Leonards NSW 2065

This leaflet was prepared in May 2023