Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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?

IMIGRAN contains the active ingredient sumatriptan succinate. IMIGRAN is used to relieve headache and other symptoms of a migraine attack. It is also used for treatment of cluster headache.

For more information, see Section <u>1. Why am I using IMIGRAN?</u> in the full CMI.

2. What should I know before I use IMIGRAN?

Do not use if you have ever had an allergic reaction to IMIGRAN 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? in the full CMI.

3. What if I am taking other medicines?

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

For more information, see 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 is a single 6 mg (0.5 mL) injection
- Cluster headache: the recommended dose for adults is a single 6 mg (0.5 mL) injection for each cluster attack. The maximum dose in 24 hours is two 6 mg injections with at least one hour between injections

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

5. What should I know while using IMIGRAN?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using IMIGRAN Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed Tell your doctor if you become pregnant or are trying to become pregnant 	
Things you should not do	 Do not change the dose of your IMIGRAN without first checking with your doctor Do not give this medicine to anyone else, even if their symptoms seem similar to yours 	
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how IMIGRAN affects yo IMIGRAN generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, IMIGRAN may cause drowsiness in some people 	
Looking after your medicine	 Store below 30°C Keep this medicine where young children cannot reach it 	

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

6. Are there any side effects?

Side effects which have been reported include temporary pain where the injection is given, nausea (feeling sick) or vomiting, pain, tingling, heat, or flushing in any part of the body, feeling of faintness or weakness, shortness of breath, shaking or tremors, visual disturbances, change in blood pressure, feeling of sleepiness, dizziness or tiredness. Serious side effects include feeling heaviness, pressure or tightness in any part of the body, including the chest or throat, feeling abnormal heart beats - too fast, too slow, or irregular heartbeats, palpitations, having a fit or convulsion, having severe pain in the stomach or abdomen and allergic reaction.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Active ingredient(s): sumatriptan succinate

Consumer Medicine Information (CMI)

This leaflet provides important information about using IMIGRAN. 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.

Where to find information in this leaflet:

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

1. Why am I using IMIGRAN?

IMIGRAN contains the active ingredient sumatriptan succinate. IMIGRAN belongs to a group of drugs called serotonin agonists.

IMIGRAN is used to relieve headache and other symptoms of a migraine attack. It should not be used to prevent migraine attacks from occurring. IMIGRAN may be used for migraine headaches with or without what is known as 'aura'. There is no information on the use of IMIGRAN in special kinds of migraine known as 'basilar migraine', 'ophthalmoplegic migraine' or 'hemiplegic migraine'.

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

IMIGRAN is also used for treatment of cluster headache.

2. What should I know before I use IMIGRAN?

Warnings

Do not use IMIGRAN 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. Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following:
 - wheezing
 - swelling of the lips/mouth
 - difficulty in breathing
 - hayfever
 - lumpy rash ("hives")
 - fainting
- you have or have had:

- heart disease, or previous heart attack
- shortness of breath, pain or tightness in the chest, jaw or upper arm
- Prinzmetal's angina
- angina, or severe chest pain or tightness
- high blood pressure that isn't under control
- severe liver disease
- a stroke
- temporary loss of oxygen to the brain also called TIAs or mini-strokes
- you have taken any of these medicines in the last 24 hours:
 - ergotamine containing preparations
 - methysergide
 - triptan containing preparations
- you have taken Monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression in the last two weeks, e.g. tranylcypromine (Parnate)

Check with your doctor if you:

- have any other medical conditions:
 - liver or kidney disease
 - epilepsy or fits
 - brain tumour, or any other condition affecting the brain
 - irregular heart beats
 - high blood pressure even if it is under control
 - high blood cholesterol levels
 - a family history of heart problems
- are allergic to:
 - food, dyes or preservatives
 - lactose, or you are lactose intolerant
 - any medicine, including any that contain sulphur (for example, sulphonamide antibiotics)
 - latex (the syringe needle shield may contain latex)
 - an antibiotic. If you are unsure if it belongs to this group, ask your doctor or pharmacist
- take any medicines for any other condition:
 - selective serotonin reuptake inhibitor (SSRI), a type of medicine used to treat depression, e.g. paroxetine (Aropax), fluoxetine (Prozac), citalopram (Cipramil, Celapram), nefazodone, sertraline, venlafaxine (Efexor)
- are over 65 years of age or under 18 years of age
- have not had your headache diagnosed as migraine by a doctor
- think that this headache is different and worse than your usual migraine
- have difficulty moving one side of your body when you have the "migraine" headache
- have not responded to your first dose of IMIGRAN

Your doctor may check if your heart is healthy before prescribing IMIGRAN. Your doctor may also decide to do tests if you get certain symptoms with IMIGRAN. This is because IMIGRAN can make certain types of heart disease worse.

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. Are there any side effects</u>?

Pregnancy and breastfeeding

Do not take IMIGRAN if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of taking IMIGRAN if you are pregnant or breastfeeding.

Children

There is no information on the use of IMIGRAN in children under 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking or have taken any other medicines in the last two weeks, 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 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.

4. How do I use IMIGRAN?

How much to use

• migraine: the recommended dose for adults aged 18 to 65 is a single 6 mg (0.5 mL) injection

If the injection doesn't help the migraine, you CANNOT use another IMIGRAN for that attack. However, if the injection does help the migraine but the migraine comes back you can use a second injection. See below for more information.

If the migraine does not get better DO NOT use another injection for the same migraine. You may take something else for the pain but do not take medicine containing ergotamine or dihydroergotamine or methysergide.

If you are not sure what to do, ask your doctor or pharmacist. He or she can tell you what you may take.

If the first IMIGRAN did not relieve your migraine, you may use IMIGRAN on another occasion to treat another migraine attack.

If the migraine improves after the injection but the headache comes back, a second injection can be used, but it must be at least an hour after the first injection. The maximum dose is two injections in 24 hours. cluster headache: the recommended dose for adults is a single 6 mg (0.5 mL) injection for each cluster attack. The maximum dose in 24 hours is two 6 mg injections with at least one hour between injections

How to use IMIGRAN

- IMIGRAN is injected under the skin using an autoinjector which is available separately to the injection
- see the instruction leaflet in the autoinjector pack for further details

When to use IMIGRAN

- it is best to use your IMIGRAN at the first sign of a migraine headache or associated symptoms:
 - when the migraine headache begins; or
 - when other symptoms of the migraine headache begin. These symptoms may be nausea (feeling sick), vomiting or your eyes becoming sensitive to light
- if you use your injection later during the migraine attack it will still work for you. Do not use your IMIGRAN before the above symptoms occur

If you use too much IMIGRAN

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

You should immediately:

- phone the Poisons Information Centre (by calling 0800 POISON or 0800 764 766), 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?

Things you should do

Tell your doctor or pharmacist that you are using IMIGRAN if you are about to be started on any new medicines.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think it was not effective and change your treatment unnecessarily.

Call your doctor straight away if you:

become pregnant or are trying to become pregnant

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

Things you should not do

 do not change the dose of your IMIGRAN without first checking with your doctor do not give this medicine to anyone else, even if their symptoms seem similar to yours

Things to be careful of

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

Driving or using machines

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

IMIGRAN generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, IMIGRAN may cause drowsiness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- store below 30°C
- protect from light.

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

Store it in a cool dry place away from moisture, heat or sunlight; 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.

When to discard your medicine

See also the autoinjector instruction leaflet for details of how to discard the injection

Needles and syringes may be hazardous and should be disposed of safely and hygienically.

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.

Are there any side effects? 6.

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
General disorders and administration site conditions:	Speak to your doctor if you have any of these less serious side
 temporary pain where the injection is given 	

•	pain, tingling, heat, or flushing in	effects and
	any part of the body	they worry you.
٠	shortness of breath	These are more

common side

IMIGRAN and

they continue

doctor.

or trouble you,

check with your

are usually only temporary. If

effects of

shortness of breath

Musculoskeletal connective tissue disorders:

shaking or tremors

Eye disorders:

visual disturbances •

Gastrointestinal disorders:

nausea (feeling sick) or vomiting •

Cardiovascular disorders:

change in blood pressure .

Nervous system disorders:

- feeling of sleepiness, dizziness or tiredness
- feeling of faintness or weakness •

Serious side effects

Serious side effects		What to do	
General disorders and administration site conditions:		Call your doctor straight away,	
•	feel heaviness, pressure or tightness in any part of the body, including the chest or throat	or go straight to the Emergency Department at your nearest	
Cardiovascular disorders:		hospital if you	
•	feel abnormal heart beats - too fast, too slow, or irregular heartbeats, palpitations	notice any of these serious side effects.	
Ner	rvous system disorders:		
•	have a fit or convulsion		
Gas	strointestinal disorders:		
•	have severe pain in the stomach or abdomen		
	nune system disorders and ergic reactions:		
• • • •	wheezing swelling of the lips/mouth difficulty in breathing hay fever lumpy rash ("hives") fainting		

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via https://pophealth.my.site.com/carmreportnz/s/

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 contains

Active ingredient	sumatriptan succinate
(main ingredient)	
Other ingredients	sodium chloride
(inactive ingredients)	water for injections

IMIGRAN does not contain lactose, sucrose or gluten.

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

What IMIGRAN looks like

IMIGRAN is a syringe containing a colourless to pale yellow solution. There are two prefilled syringes per pack. (TT50-4599/1)

The Autoinjector Pen is available separately.

Who distributes IMIGRAN

GlaxoSmithKline NZ Ltd Private Bag 106600 Downtown Auckland 1143 New Zealand

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