

Consumer Medicine Information (CMI) summary

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

1. Why am I taking IPTAM?

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

2. What should I know before I take IPTAM?

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

3. What if I am taking other medicines?

Some medicines may interfere with IPTAM 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 take IPTAM?

- Your doctor will tell you which dose of IPTAM is right for you.
- Swallow IPTAM tablets 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 take IPTAM? in the full CMI.

5. What should I know while taking IPTAM?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are taking IPTAM. 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 IPTAM tablets affect you. IPTAM may cause drowsiness, dizziness or light-headedness in some people.	
Looking after your medicine	 Store IPTAM tablets in a cool, dry place where the temperature stays below 25°C. Keep IPTAM tablets in their pack until it is time to take them. 	

For more information, see Section 5. What should I know while taking IPTAM? 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 IPTAM 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 discolouration 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 6. Are there any side effects? in the full CMI.



Active ingredient(s): sumatriptan (as succinate)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking IPTAM?

IPTAM contains the active sumatriptan succinate, which belongs to a group of medicines called serotonin agonists.

IPTAM is used to relieve a migraine attack in patients who have a stable, well-established pattern of headache symptoms, with or without what is known as 'aura'. It should not be used to prevent migraine attacks from occurring.

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

IPTAM does not work in other types of headaches which are not a migraine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that IPTAM is addictive.

2. What should I know before I take IPTAM?

Warnings

Do not take IPTAM if:

- you are allergic to sumatriptan succinate, lactose or any of the other ingredients listed at the end of this leaflet.
- you have or have had:
 - o heart disease or heart attack
 - shortness of breath, pain or tightness in 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

- o Prinzmetal's angina (an uncommon form of angina where pain is experienced at rest rather than during activity)
- o angina
- o high blood pressure
- o stroke
- o severe liver disease

you have taken any of the following migraine medicines in the last 24 hours:

- Ergotamine (e.g. Cafergot)
- o Dihydroergotamine (e.g. Dihydergot)
- o Methysergide (e.g. Deseril)
- Naratriptan (e.g. Naramig)
- o Zolmitriptan (e.g. Zomig)

you have taken any of the following medicines used to treat depression in the last two weeks:

- Monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression
- o SSRIs (selective serotonin reuptake inhibitors)
- o SNRIs (serotonin-noradrenaline reuptake inhibitors)
- the expiry date printed on the pack has passed

If you take this medicine after the expiry date, it may not work as well

• the packaging is torn or shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- are allergic to foods, dyes, preservatives or any other medicines, including any that contain sulfur (e.g. sulfonamide antibiotics).
- have or have had medical conditions such as:
 - o liver or kidney problems
 - o heart problems or a stroke
 - o risk factors including high blood pressure even if it is under control
 - o high blood cholesterol levels
 - o a family history of problems with heart or blood vessels
 - o obesity
 - o diabetes
 - o you are a male and over 40 years of age
 - o you are female and have undergone menopause
 - o you smoke
 - o suffer from epilepsy, seizures, or fits or been told that you are prone to this problem
- are under 18 or over 65 years of age
- 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.
- plan to have surgery

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell him/ her before you start taking IPTAM.

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

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking IPTAM during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking IPTAM when breastfeeding.

Children

IPTAM is not recommended for use in children and adolescents under the age of 18 as its safety and effectiveness have not been established in this age group.

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 particularly herbal preparations containing St John's Wort.

Tell your doctor also if you are taking other medicines prescribed for depression, anxiety or Obsessive Compulsive Disorder (OCD).

Some medicines may interfere with IPTAM 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 IPTAM.

4. How do I take IPTAM?

How much to take

The recommended starting dose for adults is 50 mg strength, however you may need to have your dose of this medicine increased to 100 mg. Your doctor will tell you which dose is right for you.

Do NOT take more than 300 mg IPTAM tablets in any 24 hours.

Six pink (50 mg strength) or three white (100 mg strength) tablets contain 300 mg of IPTAM.

If the first IPTAM tablet helps your migraine, but the migraine comes back later, you may take another IPTAM tablet.

Do NOT take more IPTAM tablets, or any other form of IPTAM 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 IPTAM, you may take IPTAM tablets on another occasion to treat another migraine attack. Provided there are no side effects, you can take IPTAM tablets to treat at least three separate migraine attacks before you and your doctor decide if this medicine is ineffective for you.

When to take IPTAM

It is best to take IPTAM 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 IPTAM tablets before the above symptoms

How to take it

Swallow the tablets whole with a drink of water. Do not crush or chew the tablet as it has a bitter taste.

If you take too much IPTAM

If you think that you or anyone else has taken too much IPTAM, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, 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 taking IPTAM?

Things you should do

- Tell your doctor or pharmacist 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.
- If you are about to be started on any new medicine, tell your doctor that you are taking IPTAM.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- If you take IPTAM too often, it may make your headache worse. If this happens, your doctor may tell you to stop taking IPTAM.

Driving or using machines

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

IPTAM may cause drowsiness dizziness or lightheadedness in some people (especially after the first dose). If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Store IPTAM tablets below 25°C.
- Keep IPTAM tablets in their pack until it is time to take them

If you take the tablets out of the pack they will not keep well.

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

Store it in a cool and 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and a- half metre above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not take 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.

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

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	Speak to your doctor if you have any of these less serious side
•	nausea (feeling sick) or vomiting a change in blood pressure	effects and

Less serious side effects		What to do
•	feeling of faintness	they worry
•	shaking or tremors	you.
•	uncontrolled movements	
•	shortness of breath.	

Serious side effects

Serious side effects		What to do
o b tll iri fii pp pb cc pp	lips/mouth difficulty in breathing hay fever lumpy rash (hives)	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.

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 IPTAM contains

Active ingredient (main ingredient)	Sumatriptan succinate (50 mg and 100 mg)	
Other ingredients	Lactose monohydrate	
(inactive	Cellulose – microcrystalline	
ingredients)	Croscarmellose sodium	
	Magnesium stearate	

	 Opadry II complete film coating system 40L14838 Pink [ID No. 4805 (50 mg)] Opadry II complete film coating system Y-22-7719 White [ID No. 4348 (100 mg)]
Potential allergens	Sugars as lactose

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

What IPTAM looks like

IPTAM tablets are available in 2 strengths:

- IPTAM 50 mg Pink, round, film-coated tablet debossed 'G' on one side and 'SU50' on the other side, supplied in blister packs of 4 tablets (AUST R 124086).
- IPTAM 100 mg White to off white, round, film-coated tablets debossed 'G' on one side and 'SU100' on the other side, supplied in blister packs of 2 tablets (AUST R 124087).

Who distributes IPTAM

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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