

IPTAM[®]

sumatriptan (as succinate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about IPTAM.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking IPTAM against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What IPTAM is used for

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

IPTAM tablets are used to relieve a migraine attack. They should not be used to prevent migraine attacks from occurring. IPTAM tablets 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. These medicines work by making the blood vessels normal again and ease the symptoms of migraine.

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

Your IPTAM tablets do not work in other types of headache which are not migraine.

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.

IPTAM is available only with a doctor's prescription.

There is no evidence that IPTAM is addictive.

Before you take IPTAM

When you must not take it

Do not take IPTAM if you are allergic to sumatriptan succinate or any of the ingredients listed at the end of this leaflet.

Do not take IPTAM if you 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.

Do not take IPTAM if you have taken any of these medicines in the last 24 hours:

- Ergotamine (eg Cafergot)
- Dihydroergotamine (eg Dihydergot)
- Methysergide (eg Deseril)
- Naratriptan (Naramig)
- Zolmitriptan (Zomig)

Do not take IPTAM if 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-Noradrenalin Reuptake Inhibitors) used to treat depression.

Do not take IPTAM after the expiry date (EXP.) printed on the pack.

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

Do not take IPTAM if the packaging 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.

Before you start to take it

Tell your doctor if

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

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.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Liver or kidney problems
- Problems with your heart or blood vessels, or a family history of such
- High blood pressure, even if it is under control
- High blood cholesterol levels
- Obesity
- Diabetes
- You are male and over 40 years of age
- You are female and have undergone menopause
- You smoke
- Epilepsy, seizures, or fits or been told that you are prone to this problem
- stroke

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

Tell your doctor if you plan to have surgery.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a 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).

How to take IPTAM

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

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

If the first IPTAM tablet helps your migraine, but the migraine comes back later, you may take another IPTAM tablet. Do not take more than 300 mg of IPTAM tablets in any twenty-four hour period. Six pink (50 mg strength) or three white (100 mg strength) tablets contain 300 mg of IPTAM.

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 use IPTAM tablets on another occasion to treat another migraine attack. Provided there are no side effects, you can use IPTAM tablets to treat at least three separate migraine attacks before you and your doctor decide this medicine is ineffective for you.

How to take it

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

When to take it

It is best to take your IPTAM tablet –

- (i) when the migraine 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 take your tablet later during the migraine attack it will still work for you. Do not take your IPTAM tablet before the above symptoms occur.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much IPTAM. Do this 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 taking IPTAM

Things you must do

Tell your doctor if, for some 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 IPTAM to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how IPTAM affects you.

IPTAM may cause drowsiness, dizziness or light-headedness 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.

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

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, even if the problem is not listed below.

Like other medicines, IPTAM tablets 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 taking IPTAM tablets:

- 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 and do not take any more IPTAM tablets 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 taking IPTAM tablets 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.

After taking IPTAM

Storage

Keep IPTAM where children cannot reach it.

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

Keep your tablets in the pack until it is time to take them.

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store IPTAM or any other medicine in the bathroom or near a sink.

Do not leave IPTAM in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking IPTAM, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

IPTAM tablets are available in 2 strengths:

- IPTAM 50 mg - Pink, round, film-coated tablet with 'G' on one side and 'SU50' on the other side, supplied in blister packs of 4 tablets.
- IPTAM 100 mg – White to off-white, round, film-coated tablet with 'G' on one side and 'SU100' on the other side, supplied in blister packs of 4 tablets.

Ingredients

Each IPTAM tablet contains the active ingredient sumatriptan succinate.

The tablets also contain the following inactive ingredients:

- Lactose monohydrate
- cellulose – microcrystalline
- 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)]

Supplier

IPTAM is supplied by:

**Alphapharm Pty Ltd trading as
Viartis**

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viartis.com.au

Phone: 1800 274 276

Australian registration numbers:

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IPTAM 100 mg - AUST R 124087

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mark

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