Sumatriptan RBX 50 and 100 mg

Sumatriptan Succinate Tablets

Consumer Medicine Information

What Is In This Leaflet

Please read this leaflet carefully before you start taking Sumatriptan RBX tablets.

This leaflet answers some common questions about Sumatriptan RBX tablets. 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 taking Sumatriptan RBX tablets 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 are Sumatriptan RBX tablets used for?

Sumatriptan RBX tablets contain the active ingredient sumatriptan succinate.

This medicine belongs to a group of drugs called serotonin agonists.

Sumatriptan RBX tablets are used to relieve a migraine attack. They should not be used to prevent migraine attacks from occurring.

Sumatriptan RBX 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.

Sumatriptan RBX tablets work by making those vessels normal again and ease the symptoms of migraine.

Your Sumatriptan RBX tablets do not work in other types of headache which are not a migraine.

Sumatriptan RBX tablets are not addictive.

Before you take Sumatriptan RBX tablets

Do not take if:

You must not take Sumatriptan RBX tablets 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 Dihydergot)
  - 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.
- **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 allergic to lactose.**
- **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 breast feeding, 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 take Sumatriptan RBX tablets?

Take your medicine as your doctor has told you. The label on the pack will tell you how many tablets to take and how often you should take them. If you do not understand what you should do, ask your doctor or pharmacist.

How much to take

The recommended starting dose for adults is 50 mg; however you may need to have your dose of Sumatriptan RBX tablets increased to 100 mg. Your doctor will tell you which dose is right for you. If the first Sumatriptan RBX tablet helps your migraine, but the migraine comes back later, you may take another Sumatriptan RBX tablet. Do not take more than 300 mg of Sumatriptan RBX tablets in any twenty-four hours. Six pink (50 mg strength) or three white (100 mg strength) tablets contain 300 mg.

Do not take more Sumatriptan RBX tablets, or any other form of Sumatriptan, 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 Sumatriptan RBX tablets, you may use Sumatriptan RBX tablets on another occasion to treat another migraine attack.

Provided there are no side effects, you can use Sumatriptan RBX 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

Your Sumatriptan RBX tablet should be swallowed with a drink 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 Sumatriptan RBX 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 Sumatriptan RBX tablet before the above symptoms occur.

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

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think you or anyone else may have taken too many Sumatriptan RBX tablets, 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 Sumatriptan RBX tablets

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, Sumatriptan RBX tablets may cause drowsiness in some people.

Be careful driving or operating machinery until you know how Sumatriptan RBX tablets affect you.
If you use Sumatriptan RBX tablets too often, it may make your headache worse. If this happens, your doctor may tell you to stop taking Sumatriptan RBX tablets.

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 taking Sumatriptan RBX tablets even if the problem is not listed below.

Like other medicines, Sumatriptan RBX 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 Sumatriptan RBX 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, or seek urgent medical attention, and do not take any more Sumatriptan RBX 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 Sumatriptan RBX 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.

How do I store Sumatriptan RBX tablets?

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

Keep Sumatriptan RBX tablets in the blister pack in a cool, dry place where it stays below 25°C.

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

Keep Sumatriptan RBX tablets in their pack until it is time to take them.

Return any unused or expired medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Sumatriptan RBX tablets come in 50 mg & 100 mg:

- **Sumatriptan RBX 50 mg**
  (AUST R 154819)
  Pink coloured, capsule shaped biconvex film coated tablets, plain on both sides. In packs of 2 & 4.
- **Sumatriptan RBX 100 mg**
  (AUST R 154818)
  White to off-white coloured, capsule shaped biconvex film coated tablets, plain on both sides. In packs of 2.

Ingredients

Active ingredients

- Sumatriptan RBX 50 mg contains sumatriptan succinate equivalent to 50 mg sumatriptan per tablet
- Sumatriptan RBX 100 mg contains sumatriptan succinate equivalent to 100 mg sumatriptan per tablet

Inactive ingredients

- Lactose, cellulose microcrystalline, croscarmellose sodium, hypromellose and magnesium stearate.
- Sumatriptan RBX 50 mg also contain OPADRY complete film coating system 03K54036 PINK.
- Sumatriptan RBX 100 mg also contain OPADRY complete film coating system 03A58900 WHITE.

Sumatriptan RBX tablets do not contain gluten or sugar.

Name and Address of the Sponsor

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Name and Address of the Distributor

Ranbaxy Australia Pty Ltd
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Date of Approval

TGA approval:
26th March 2010

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