

ZOLTRIP

Zolmitriptan

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about ZOLTRIP. It does not contain all the information that is known about ZOLTRIP. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZOLTRIP against the benefits they expect it will 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 ZOLTRIP is for

ZOLTRIP belongs to a group of medicines called serotonin agonists. These medicines are used to relieve migraine.

Migraine is thought to be caused by the widening of certain blood vessels in the brain. ZOLTRIP makes the blood vessels narrower to ease the migraine.

Some people have a warning stage called 'aura' before the migraine headache starts. Aura can include numbness in the face or down one arm, changes in mood, or problems with eyesight such as seeing blank spots or flashing lights.

ZOLTRIP can be used in migraine with or without aura. It should not be used to treat types of migraine

called 'hemiplegic' or 'basilar' migraine.

ZOLTRIP does not work in headaches that are not migraine.

Your doctor will have explained why you are being treated with ZOLTRIP and told you what dose to take.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

ZOLTRIP is not addictive.

Before you take ZOLTRIP

When you must not take it

Do not use ZOLTRIP if you are pregnant or breastfeeding unless your doctor says so.

The safety of taking this medicine when you are pregnant is unknown.

Do not give ZOLTRIP to children.

There is no experience of its use in children under 12 years of age. One study in children aged 12 to 17 years indicated no benefit with ZOLTRIP treatment.

Do not use ZOLTRIP after the use by (expiry) date printed on the pack.

It may have no effect at all, or an unexpected effect, if you take it after the expiry date.

Do not use ZOLTRIP if the packaging is torn or shows signs of tampering.

Do not give this medicine to anyone else.

Before you start to use it

You must tell your doctor if:

1. you have any allergies to

- any ingredient listed at the end of this leaflet
 - any other substances
- If you have an allergic reaction, you may get a skin rash, hayfever, difficulty breathing or feel faint.

2. you have or have had any of these medical conditions

- high blood pressure
- a feeling of tightness, pressure or heaviness in the chest
- a heart attack, other heart problems or a family history of heart problems
- a stroke or dizzy spells caused by lack of blood flow to the brain
- blood vessel problems that cause poor circulation in the arms or legs
- kidney or liver disease
- high cholesterol levels in the blood
- diabetes

It may not be safe for you to take ZOLTRIP if you have any of these conditions. Your doctor may decide to do tests to check if your heart is healthy before prescribing ZOLTRIP tablets.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- other medicines for migraine, such as sumatriptan, naratriptan, ergotamine, dihydroergotamine or methysergide
- medicines for depression
- cimetidine for the treatment of indigestion or stomach ulcers
- antibiotics known as quinolones (eg noroxin).
- St John's Wort (*Hypericum perforatum*)
- any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

These medicines may affect the way ZOLTRIP works. Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of these things, tell them before you take any ZOLTRIP.

Taking ZOLTRIP

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

The usual dose is one tablet (2.5 mg) as soon as you feel the migraine headache start.

If your migraine is still present after two hours, or if it returns within 24 hours, you can take another tablet.

Do not take more than 10 mg (four 2.5 mg tablets) in twenty-four hours.

Swallow your ZOLTRIP tablets whole with a glass of water.

You can take them before or after food.

When to take it

You can take ZOLTRIP when you feel the headache start or after it has already begun.

ZOLTRIP tablets should only be taken to treat the migraine headache after it has started. They should not be used to prevent the migraine attacks from occurring.

Overdose

Immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to casualty at your nearest hospital if you think that you or anyone else may have taken too much ZOLTRIP even if there are no signs of discomfort or poisoning.

While you are taking ZOLTRIP

Things you must do

If you go into hospital tell the staff if you have taken any ZOLTRIP that day.

If you are about to start taking any other medicine, tell your doctor and pharmacist that you are taking ZOLTRIP.

Things you must not do

Do not give ZOLTRIP to anyone else, even if they have the same condition as you.

Do not use ZOLTRIP tablets to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

ZOLTRIP can make some people feel dizzy or sleepy. Make sure you know how you react to ZOLTRIP before you do anything that could be dangerous if you are dizzy or sleepy.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZOLTRIP.

ZOLTRIP helps most people with migraine, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- increased feeling or sensitivity, especially in the skin
- feeling warm
- feelings of heaviness, tightness, pain or pressure in the throat, neck, arms or legs
- unusual tiredness or weakness
- aching muscles not caused by exercise
- dizziness
- nausea
- stomach pain
- vomiting
- headache
- palpitations (irregular heart beat)
- sleepiness
- dry mouth

These are all common and mild side effects of ZOLTRIP.

If any of the following happen, stop taking ZOLTRIP and tell your doctor immediately or go to the emergency department at your nearest hospital.

- wheezing, difficulty in breathing, swelling of the lips or mouth, a lumpy rash (hives) or fainting.
- a feeling of tightness, pressure or heaviness in the chest

- irregular heart beats/ increased heart rate
- numbness or loss of strength of the arms or legs, headache, dizziness, confusion, visual disturbance, difficulty swallowing, slurred speech or loss of speech
- bloody diarrhoea or prolonged stomach pain

These are serious side effects. If you have them, you may have had a serious reaction to ZOLTRIP. You may need urgent medical attention or hospitalisation.

Serious side effects are rare.

Some people may get other side effects not listed above.

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

After using ZOLTRIP

Storage

Keep your tablets in the blister pack until it is time to take them. If you take ZOLTRIP out of the blister pack it will not keep well.

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

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What ZOLTRIP looks like

ZOLTRIP 2.5 mg are light pink, round, film-coated tablets, debossed with '2.5' on one side and plain on the other. ZOLTRIP 2.5 mg tablets are presented in blister packs containing 2 tablets.

Ingredients

Each tablet contains 2.5 mg zolmitriptan as the active ingredient plus the following inactive (excipient) ingredients:

- microcrystalline cellulose
- lactose
- sodium starch glycollate type A
- magnesium stearate
- Opadry Pink 02G84574 (hypromellose, titanium dioxide, macrogol 400, macrogol 8000, iron oxide red)

Sponsor

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