

ZOLTRIP

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 ZOLTRIP?

ZOLTRIP contains the active ingredient zolmitriptan.

ZOLTRIP is used to relieve migraine.

For more information, see Section [1. Why am I using ZOLTRIP?](#) in the full CMI.

2. What should I know before I use ZOLTRIP?

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

Tell your doctor if you have any allergies or other medical conditions.

For more information, see Section [2. What should I know before I use ZOLTRIP?](#) in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZOLTRIP?

- 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.
- ZOLTRIP can be taken with or without food.
- **Do not take more than 10 mg (four 2.5 mg tablets) in twenty- four hours.**
- More instructions can be found in Section [4. How do I use ZOLTRIP?](#) in the full CMI.

5. What should I know while using ZOLTRIP?

Things you should do	<ul style="list-style-type: none">• Tell any doctors, dentists and pharmacists who are treating you that you are taking ZOLTRIP.
Things you should not do	<ul style="list-style-type: none">• Do not take ZOLTRIP to treat any other conditions unless your doctor says so.• Do not give this medicine to anyone else, even if their symptoms are similar to yours.
Driving or using machines	<ul style="list-style-type: none">• ZOLTRIP may cause dizziness or drowsiness in some people and affect alertness. If affected, do not drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Keep ZOLTRIP Tablets in a cool dry place where the temperature is below 25°C.

For more information, see Section [5. What should I know while using ZOLTRIP?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The serious side effects are: signs of allergy; fast or irregular heart beats; a feeling of tightness in the chest; 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. The common side effects are increased feeling or sensitivity in the skin; feeling warm, feelings of heaviness in the throat, neck arm or legs; unusual tiredness or weakness; aching muscles; headache; dizziness; flushing; sleepiness; stomach pain; vomiting or nausea dry mouth.

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.

ZOLTRIP Tablets

Active ingredient: *Zolmitriptan*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZOLTRIP tablets. It does not contain all 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 risks of you taking ZOLTRIP against the benefits this medicine is expected to have for you.

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 ZOLTRIP.

Keep this leaflet with your medicine. You may need to read it again.

Where to find information in this leaflet:

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

1. Why am I using ZOLTRIP?

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.

Use in Children

There is no experience of its use in children under 12 years of age.

2. What should I know before I use ZOLTRIP?

Warnings

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. One study in children aged 12 to 17 years indicated no benefit with ZOLTRIP treatment.

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

Do not give this medicine to anyone else.

If you are not sure whether you should be taking ZOLTRIP, talk to your doctor.

Do not use ZOLTRIP if the packaging is torn or shows signs of tampering. Do not use ZOLTRIP beyond the expiry date printed on the pack.

Check with your doctor or pharmacist if you:

- have allergies to any other medicines, foods, preservatives or dyes, or any ingredients listed at the end of this leaflet. If you have an allergic reaction, you may get a skin rash, hayfever, difficulty breathing or feel faint.
- have or have had any of the following 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.

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 [6. Are there any side effects?](#)

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.

Some medicines may be affected by ZOLTRIP or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will advise you.

In particular, you should tell your doctor if you are taking or have recently taken medicines like:

- 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*).

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ZOLTRIP.

4. How do I use ZOLTRIP?

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

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

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.

Your doctor may prescribe another dose of ZOLTRIP depending on your condition and how you respond to this medicine.

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

When to take / use ZOLTRIP

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.

How to take ZOLTRIP?

- Swallow the tablet whole with a full glass of water.
- ZOLTRIP can be taken with or without food.
- If you accidentally take a larger dose than recommended, tell your doctor immediately.
- If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you use too much ZOLTRIP

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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. You may need urgent medical attention.

You may need urgent medical attention.

5. What should I know while using ZOLTRIP?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking ZOLTRIP.

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

Things you should not do

- Do not take ZOLTRIP to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you

Driving or using machines

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.

Looking after your medicine

- Keep ZOLTRIP tablets in the original pack until it is time to take them.
- Keep ZOLTRIP tablets in a cool dry place where the temperature is below 25°C.

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

Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

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.

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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> 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 headache sleepiness dizziness nausea stomach pain vomiting dry mouth palpitations (irregular heart beat) 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> 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 	<p>Tell your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

<ul style="list-style-type: none"> 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 	<p>these serious side effects.</p> <p>The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.</p>
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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.

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 available with a doctor's prescription.

What ZOLTRIP contains

Active ingredient (main ingredient)	Zolmitriptan
Other ingredients (inactive ingredients)	ZOLTRIP tablets contain: <ul style="list-style-type: none"> microcrystalline cellulose lactose sodium starch glycollate type A magnesium stearate Opadry Pink 02G84574 (hypromellose, titanium dioxide, macrogol 400, macrogol 8000, iron oxide red)
Potential allergens	Sugars as lactose

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

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

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.

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Who distributes ZOLTRIP

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

www.arrotex.com.au

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