

# APO-Zolmitriptan

Contains the active ingredient zolmitriptan

## Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

### What is in this leaflet

#### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about zolmitriptan. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

#### Keep this leaflet with your medicine.

You may want to read it again.

### What this medicine is used for

The name of your medicine is APO-Zolmitriptan Tablets. It contains the active ingredient zolmitriptan.

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

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

This medicine is available only with a doctor's prescription.

#### How it works

Migraine is thought to be caused by the widening of certain blood vessels in the brain. Zolmitriptan 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.

Zolmitriptan can be used in migraine with or without aura. It should not be used to treat types of migraine called 'hemiplegic' or 'basilar' migraine.

Zolmitriptan does not work in headaches that are not migraine.

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

There is no evidence that this medicine is addictive.

### Use in 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 zolmitriptan treatment.

### Before you take this medicine

#### When you must not take it

#### Do not take this medicine if:

#### You have or have had any of the following:

- **You are pregnant.**  
The safety of taking this medicine when you are pregnant is unknown.
- **You are breastfeeding.**  
The safety of taking this medicine whilst breastfeeding is unknown.
- **You are hypersensitive to, or have had an allergic reaction to, zolmitriptan or any of the ingredients listed at the end of this leaflet.**  
Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.  
**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

#### Before you start to take it

#### Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
  - 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 zolmitriptan if you have any of these conditions. Your doctor may decide to do tests to check if your heart is healthy before prescribing zolmitriptan tablets.**
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with zolmitriptan. These include:

- 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

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

Other medicines not listed above may also interact with zolmitriptan.

### How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information 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.**

#### How to take it

**Swallow your zolmitriptan tablets whole with a glass of water.**

#### When to take it

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

Zolmitriptan 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.

It does not matter if you take it before, with or after food.

#### If you take too much (overdose)

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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## While you are taking this medicine

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### Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- if you go into hospital tell the staff if you have taken any zolmitriptan that day
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

### Things you must not do

#### Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.

### Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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

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## Possible side effects

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Tell your doctor as soon as possible if you do not feel well while you are taking zolmitriptan or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

#### Tell your doctor if you notice any of the following:

- 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 zolmitriptan.

#### Tell your doctor as soon as possible if you notice any of the following.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- an allergic reaction - symptoms may include some or all of the following:
  - wheezing, difficulty in breathing, swelling of the lips or mouth, a lumpy rash (hives) or fainting
  - cough, shortness of breath, wheezing or difficulty breathing
  - swelling of the face, lips, tongue, throat or other parts of the body
  - rash, itching or hives on the skin
  - fainting
  - hay fever-like symptoms.
- a feeling of tightness, pressure or heaviness in the chest
- irregular heartbeats / 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

Other side effects not listed above may occur in some patients.

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## Storage and disposal

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### Storage

#### Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

#### Keep your medicine in a cool dry place where the temperature will stay below 25°C.

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.** Heat and dampness can destroy some medicines.

#### Keep this medicine where 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

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### What APO-Zolmitriptan Tablets look like

2.5 mg tablets - light pink, round, film-coated tablets, debossed with '2.5' on one side and plain on the other.

Blister pack of 2 or 6 tablets.

### Ingredients

Each tablet contains 2.5 mg zolmitriptan as the active ingredient.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- lactose
- sodium starch glycollate type A
- magnesium stearate
- Opadry complete film coating system 02G84574 Pink

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

### Australian Registration Numbers

APO-Zolmitriptan 2.5 mg tablets (blister pack): AUST R 200878.

### Distributor

**Apotex Pty Ltd**  
16 Giffnock Avenue  
Macquarie Park NSW 2113

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