

APO-Zonisamide

Contains the active ingredient Zonisamide

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 Zonisamide. 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.

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-Zonisamide capsules. It contains the active ingredient Zonisamide.

It is used to treat certain types of epilepsy in adults. Zonisamide may be used:

- on its own to treat seizures in adults,
- with other antiepileptic medicines to treat seizure in adults.

Zonisamide is used in partial seizure that affects only one part of brain, with or without generalized seizures that may affect the whole brain.

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

Epilepsy is caused by a disruption in the electrical activity of the brain. The abnormal electrical impulses occur due to altered levels of some chemicals in the brain. Zonisamide can control brain chemicals which send signals to nerves so that seizures do not happen.

There is no evidence that this medicine is addictive.

Use in children

The safety and efficacy of zonisamide in children under 18

years of age have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, zonisamide and sulfonamide drugs including frusemide and bumetanide (diuretic medicines) or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: 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; .

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.

Zonisamide capsules must not be given to anyone who is unconscious or in coma.

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:
 - suicidal behaviour or thoughts
 - reduced white blood cell count
 - metabolic acidosis (a condition that causes too much acid in the body)
 - kidney disease or kidney stones
 - liver disease
 - pancreatitis (inflammation of the pancreas)
 - muscle weakness or pain.
3. You have recently lost weight or weigh less than 40kg.
4. 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.
5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
6. You are planning to have surgery..
7. You are currently receiving or are planning to receive dental treatment.
8. 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.

Taking other medicines

Some medicines may interact with zonisamide. These include:

- phenytoin
- carbamazepine
- phenobarbitone

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

Other medicines not listed above may also interact with zonisamide.

Some medicines may affect the way other medicines work. They may also react with Zonisamide capsules resulting in untoward or sometimes dangerous side effects. Your doctor or pharmacist will be able to tell you which medicines are safe to take with zonisamide capsules.

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

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor or pharmacist.

The usual starting dose is 50mg daily taken in two divided doses. The dose will be gradually increased at intervals of one or two weeks, to a daily dose of between 300mg and 500mg per day. Some patients respond to lower doses.

How to take it

Zonisamide capsules must be swallowed whole with water. Do not chew the capsules.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

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

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

It helps to control your condition, but does not cure it. Therefore, it is important that you keep taking zonisamide capsules every day. Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

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.

Signs of overdose include drowsiness and sleepiness. You should not drive at this time.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

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

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.

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.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

If you stop taking zonisamide capsules suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of zonisamide capsules you take each day before stopping the medicine completely.

Things to be careful of

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

As with other antiepileptic medicines, zonisamide capsules may cause drowsiness in some people. Make sure you know how you react to zonisamide capsules before you drive, operate machinery, or do anything else that could be dangerous.

Make sure you keep cool in hot weather and drink plenty of water. This will help reduce the risk of kidney stones.

Persons taking this medicine may be more likely to think about killing themselves or actually trying to do so, especially when they are first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using zonisamide who talks about or shows signs of wanting to kill him or herself.

If you or someone you know demonstrates any of the following warning signs of suicide-related behaviour while taking this medicine, contact a healthcare provider immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- new or worse depression
- new or worse anxiety
- panic attacks
- trouble sleeping (insomnia)
- increase in aggressive behaviour, irritability or agitation
- acting on dangerous impulses
- extreme increase in activity and talking (mania)
- other unusual changes in behaviour or mood.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking zonisamide 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 mild side effects:

- drowsiness or sedation (especially early on in the treatment)
- loss of appetite
- loss of weight
- dizziness
- nausea
- agitation or irritability
- double vision
- depression
- poor muscle coordination
- confusion
- poor memory
- stomach pains
- diarrhoea
- speech abnormalities
- skin rashes, fever and allergic reactions
- anxiety
- nervousness
- tremor
- sounds in one ear or both ears
- constipation
- dry mouth
- changes in taste
- joint pain
- flu syndrome
- headaches
- shortness of breath

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

These may be serious side effects and you may need medical attention:

- less sweating and increase in your body temperature (fever)
- suicidal thoughts or actions in some people.

- increased level of acid in your blood (metabolic acidosis)

If left untreated, metabolic acidosis can cause brittle or soft bones, kidney stones. Your doctor should do a blood test to measure the level of acid in your blood before and during your treatment.

- problems with your concentration, attention, memory, thinking, speech, or language
- blood cell changes such as reduced red and white blood cell counts that may cause infections or a bleeding tendency.

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:

- thoughts about suicide or dying
- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behaviour or mood
- fever
- sore throat or sores in your mouth
- unusual bruising
- signs of increased acid level in the blood:
- headaches
- drowsiness
- shortness of breath
- loss of appetite
- sharp abdominal pain (kidney or urinary stones)
- muscle pain or weakness

- loss of balance or difficulty walking
- seizure or convulsion

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

Allergic reactions

If you think you are having an allergic reaction to zonisamide, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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

Storage and disposal

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.

Product description

What APO-Zonisamide Capsules looks like

25mg Capsules:

White - White opaque coloured hard gelatin capsules of size "4" imprinted with "I" on cap and "22" on body with black ink containing white to off white powder.

Blister packs of 56 capsules

50mg Capsules:

Gray-White opaque coloured hard gelatin capsules of size "3" imprinted with "I" on cap and "21" on body with black ink containing white to off white powder.

Blister packs of 56 capsules

100mg Capsules:

Red-White opaque coloured hard gelatin capsules of size "1" imprinted with "I" on cap and "20" on body with black ink containing white to off white powder.

Blister packs of 56 capsules

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each capsule contains 25mg, 50mg and 100mg of Zonisamide as the active ingredient.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- hydrogenated vegetable oil
- sodium lauryl sulphate
- silica colloidal anhydrous.

The hard capsule shell contains:

- gelatine
- titanium dioxide (E171)
- water
- black iron oxide (E172) (only in 50mg capsules)
- sunset yellow FCF (E110) (only in 100mg capsules)

- allura red AC (E129) (only in 100mg capsules)

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

Australian Registration Numbers

APO-Zonisamide 25mg Capsules
(Blister): AUST R 265578,
APO-Zonisamide 50mg Capsules
(Blister): AUST R 265574,
APO-Zonisamide 100mg capsules
(Blister): AUST R 265577.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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