

# **APO-Zonisamide**

Contains the active ingredient Zonisamide

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## **Consumer Medicine Information**

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

## **What is in this leaflet**

This leaflet answers some common questions about this medicine. 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 this medicine 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 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

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.

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.

There is no evidence that this medicine is addictive.

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

## **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 have an allergy to:**

- any medicine containing zonisamide
- sulfonamide drugs including frusemide and bumetanide (diuretic medicines)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits with you.

**Do not breastfeed if you are taking this medicine or for one month after stopping.**

The active ingredient in this medicine passes into breast milk and there is a possibility that your baby may be affected.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

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

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

## **Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- 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

**Tell your doctor if you have recently lost weight or weigh less than 40kg.**

**Tell your doctor if you are pregnant or plan to become pregnant or start breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

## **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may interact with zonisamide. These include:

- phenytoin
- carbamazepine
- phenobarbitone

These medicines may be affected by zonisamide 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **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.

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

## **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.

**If you are taking zonisamide on its own:**

The usual starting dose is 100 mg daily taken once a day.

This may be increased by up to 100 mg at intervals of two weeks.

The usual daily dose is 300 mg once a day.

**If you are taking zonisamide with other antiepileptic medicines:**

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 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 your medicine at about the same time each day.**

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

It does not matter if you take this medicine before or after food.

## **How long to take it for**

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

Zonisamide helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

## **If you forget to take it**

**If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.**

**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 the dose that you missed.**

This may increase the chance of you experiencing side effects.

**If you are not sure what to do, ask your doctor or pharmacist.**

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

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

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

**Symptoms of an overdose may include drowsiness and sleepiness. You should not drive at this time.**

# **While you are taking this medicine**

## **Things you must do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

Zonisamide may affect other medicines used during surgery.

**If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

Zonisamide may interfere with the results of some tests.

**Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure zonisamide is working and to prevent unwanted side effects.

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

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

## **Things you must not do**

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking your medicine or lower the dosage without 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.

**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.**

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.

**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

## **Side effects**

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

**Tell your doctor if you notice any of the following side effects:**

- drowsiness or sedation (especially early in treatment)
- loss of appetite or loss of weight
- dizziness
- nausea
- agitation, irritability or anxiety

- double vision
- depression
- poor muscle coordination
- confusion or poor memory
- stomach pains
- diarrhoea or constipation
- speech abnormalities
- skin rashes, fever and allergic reactions
- nervousness
- tremor
- sounds in one ear or both ears
- dry mouth or changes in taste
- joint pain
- flu-like syndrome
- headaches
- shortness of breath

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

- less sweating and increase in your body temperature (fever)
- suicidal thoughts or actions in some people
- have an unexplained skin rash, as this could develop into a more severe skin rash or skin peeling
- feel unusually tired or feverish, have a sore throat, swollen glands, or find that you bruise more easily
- glaucoma, which is a blockage of fluid in the eye causing increased pressure in the eye – eye pain, blurred vision or decreased vision may occur and can be signs of glaucoma
- 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

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

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- thoughts about suicide or dying; attempting 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, or pain on urinating (kidney or urinary stones)
- muscle pain or weakness
- loss of balance or difficulty walking
- seizures or convulsions
- symptoms of an allergic reaction which 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

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

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

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

## **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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## **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. AUST R 265578.

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. AUST R 265574.

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. AUST R 265577.

Blister packs of 56 capsules

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

## **Ingredients**

Each capsule contains zonisamide as the active ingredient.

It also contains the following inactive ingredients:

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

The hard-capsule shell contains:

- gelatine (contains sulfites)

- 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.

## **Sponsor**

Apotex Pty Ltd

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