

# Apo-Primidone

*primidone*

250mg Tablets

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## What is in this leaflet

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Please read this leaflet carefully before you start using Apo-Primidone.

This leaflet answers some common questions about Apo-Primidone. 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 using Apo-Primidone against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

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

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## What Apo-Primidone is used for

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The name of your medicine is Apo-Primidone tablet. It contains the active ingredient Primidone.

Apo-Primidone is used to:

- control epilepsy
- other types of seizures and jerks

Epilepsy is a condition where you have repeated seizures (fits). There are many types of seizures and they can range from mild to severe.

Apo-Primidone is a barbiturate and belongs to a group of medicines called antiepileptics. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that the seizures do not happen.

Apo-Primidone may be used alone or in combination with other medicines to treat your condition.

Your doctor may have prescribed Apo-Primidone for another reason.

Ask your doctor if you have any questions about why Apo-Primidone has been prescribed for you.

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

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## **Before you use Apo-Primidone**

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### ***When you must not use it***

Do not use Apo-Primidone if:

- **You are hypersensitive to, or have had an allergic reaction to Primidone or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; 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.**

- **You have the following health/medical conditions:**
  - Porphyria (a rare blood pigment disorder)
- **The expiry date (EXP) printed on the pack has passed.**

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using Apo-Primidone, talk to your doctor.

### ***Before you start to use it***

Tell your doctor if:

1. **You have allergies to:**
  - any other barbiturate
  - other medicines used to treat fits or epilepsy
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.

**2. You have or have had any medical conditions, especially the following:**

- Liver problems
- Kidney problems
- Lung problems

**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. Primidone may affect your developing baby if you take it during pregnancy. However, it is very important to control your fits while you are pregnant.

**4. You are currently breastfeeding or you plan to breast-feed.**

Primidone can pass into breast milk and may affect your baby. If you do breast-feed, watch your baby carefully. If your baby becomes sleepy don't breast-feed again until you speak to your doctor. Your doctor will discuss with you the risks and benefits of taking primidone when breast-feeding.

**5. You are planning to have surgery or an anaesthetic.**

**6. You are currently receiving or are planning to receive dental treatment.**

If you have not told your doctor about any of the above, tell them before you start using Apo-Primidone.

### ***Taking other medicines***

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Primidone.

Some medicines may interfere with Apo-Primidone. These include:

- medicines for epilepsy or convulsions
- medicines used to thin your blood e.g. warfarin
- oral contraceptives (birth control pills)

These medicines may be affected by Apo-Primidone, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interact with Apo-Primidone.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Primidone.

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## How to use Apo-Primidone

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

The label should be carefully read

### ***How much to take***

Your doctor will decide how much Apo-Primidone you need to take. Your dose will be adjusted according to your response.

Apo-Primidone is usually taken twice a day.

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.

### ***How to take it***

Swallow the tablet(s) with a glass of water.

### ***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.

Take Apo-Primidone regularly. If you do not take it regularly your seizures will not be well controlled.

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

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

Abrupt cessation of primidone should be avoided. The abrupt stopping may cause fits or withdrawal reaction. Primidone should be withdrawn gradually over one to two weeks, if possible.

Your doctor will advise you when you can stop taking Apo-Primidone completely.

### ***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.

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## **While you are using Apo-Primidone**

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### ***Things you must do***

Immediately stop taking Apo-Primidone and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Primidone.

Take your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Apo-Primidone.

Always discuss with your doctor any problems or difficulties during or after taking Apo-Primidone.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Primidone to last weekends and holidays.

### ***Things you must not do***

**Do not give Apo-Primidone to anyone else, even if they have the same condition as you.**

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

**Do not stop taking your medicine, or change the dosage, without first checking with your doctor.**

**Do not take any other medicine while you are taking Apo-Primidone without first telling your doctor.**

**Do not take Apo-Primidone for a longer time than your doctor has prescribed.**

### ***Things to be careful of***

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Apo-Primidone affects you.

Primidone can make some people sleepy and it may take you longer to react in certain situations. Make sure you know how you react to primidone before you do any dangerous activities or if you will need to react quickly.

Be careful when drinking alcohol as Apo-Primidone may increase the effects of alcohol.

Taking Apo-Primidone may increase the risk of suicidal thoughts and behaviour. Please report any signs of depression, unusual changes in moods, behaviour and presence of suicidal thoughts or self-harm to your doctor.

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

### **Warning signs of suicide:**

**All thoughts or talk about suicide or violence are serious. If you or someone you know is showing the following warning signs, either contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment:**

- **Thoughts or talk about death or suicide**
- **Thoughts or talk about self-harm or doing harm to others**
- **Any recent attempts of self-harm**
- **An increase in aggressive behaviour, irritability or agitation**

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## **In case of overdose**

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

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Primidone.

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

If you take too much primidone, it will probably make you feel unsteady and drowsy, you may struggle to breath properly. You may lose consciousness.

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## Side Effects

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Primidone or if you have any questions or concerns.

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 adverse effects.

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

Primidone is generally well tolerated.

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

This list includes the most common side effects. Mostly, these are mild and transient:

- Drowsiness
- Tiredness
- Headache
- Nausea or vomiting
- Visual disturbances
- Dizziness or unsteadiness when walking

These things may happen when you first start taking Apo-Primidone but usually go away after a while

### **Tell your doctor immediately if you notice any of the following.**

These may be serious side effects. You may need medical attention.

- Painful joints
- Yellowing of the skin and/or eyes
- Fever
- Bleeding or bruising under the skin
- Suicidal thoughts or behaviour
- Unusual changes in moods
- Worsening of depression

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

- Rash, itching or hives
- Swelling of the face, lips, tongue or throat

These are serious side effects. You may need urgent medical attention or hospitalization.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

### **Long term effects**

Apo-Primidone may affect the metabolism of Vitamin D which is important for bone health. A deficiency in Vitamin D can lead to diminished bone health and possible osteoporosis. If you are on long term treatment with Apo-Primidone, your doctor may decide to monitor your bone density and suggest supplements to assist with your bone health.

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## **After using Apo-Primidone**

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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.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

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## **Product description**

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### ***What it looks like***

Apo-Primidone 250mg tablets are white, round (diameter of 10.4mm), flat with bevelled edge tablets, scored and engraved APO over 250 on one side.



Apo-Primidone 250mg tablets are available in bottles of 100 or 500 tablets.

\* Not all pack sizes may be available.

## ***Ingredients***

### Active ingredient:

Each tablet contains 250mg of Primidone as the active ingredient.

### Inactive ingredients:

- Methylcellulose
- Croscarmellose sodium
- Magnesium stearate
- Colloidal silicon dioxide

This medicine is gluten free.

This medicine is lactose free.

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## **Sponsor Details**

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Apo-Primidone is supplied in New Zealand by:

**Apotex NZ Ltd**  
32 Hillside Road  
Glenfield  
AUCKLAND 0627

Telephone: (09) 444 2073

Fax: (09) 444 2951

Email: [NZcustomerservice@apotex.com](mailto:NZcustomerservice@apotex.com)

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## **Date of Preparation**

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This leaflet was prepared on 23 August 2018.