

MYSOLINE®

Primidone

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions people ask about Mysoline. It does not contain all the information that is known about Mysoline.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Mysoline 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 MYSOLINE IS FOR

Mysoline is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

Mysoline 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 seizures do not happen.

Mysoline may be used alone, or in combination with other medicines, to treat your condition.

Follow all directions given to you by your doctor.

They may differ from the information in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

BEFORE YOU USE MYSOLINE

When you must not use it

Do not take Mysoline after the use by (expiry) date printed on the pack.

It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take Mysoline if the packaging is torn or shows signs of tampering.

Do not use it 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.

Before you start to use it

You must tell your doctor if:

1. You have any allergies to:

- Primidone or any other barbiturates
- Other medicines used to treat fits or epilepsy
- Any of the other ingredients listed at the end of this leaflet
- Any other medicines
- Any other substances, such as foods, preservatives or dyes

If you have an allergic reaction, you may experience a skin rash, hayfever, difficulty breathing or feel faint.

2. You have or have ever had:

- Porphyria (a rare blood pigment disorder)
- Liver problems
- Kidney problems
- Lung problems

Your doctor will decide if you should take Mysoline if you have any of these conditions.

If you are pregnant or intend to become pregnant while taking Mysoline, you must talk to your doctor.

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

If it is necessary for you to take Mysoline, your doctor can help you decide whether or not to take it during pregnancy.

Talk to your doctor before breastfeeding while taking Mysoline.

Mysoline passes into breast milk and may affect your baby.

If you do breastfeed, watch your baby carefully.

If your baby becomes sleepy don't breastfeed again until you speak to your doctor.

Taking other medicines

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

Some medicines may be affected by Mysoline, or may affect how well

Mysoline works. This includes (but is not limited to):

- Medicines for epilepsy or convulsions
- Medicines used to thin your blood eg. Warfarin
- Anti-infective, anti-viral and anti-fungal medicines
- Medicines that affect the heart rhythm
- Medicines that are derived from natural or synthetic hormones
- Medicines to treat pain
- Medicines to treat mood disorders, including anti-depressants and anti-psychotics
- Medicines for the treatment of cancer
- Oral contraceptives (birth control pills)

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

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

TAKING MYSOLINE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day.

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

How much to take

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

Mysoline is usually taken twice a day.

Swallow your Mysoline tablets with a full glass of water.

If you forget to take it

If you miss a dose take it as soon as you remember, as long as it is at least 6 hours before the next dose is due. Then go back to taking it as you would normally.

If it is less than 6 hours to the next dose, skip the dose you have missed and take your next dose at the usual time. Then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

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

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

OVERDOSE

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

If you take too many Mysoline tablets you will probably feel unsteady and drowsy. You may lose consciousness.

WHILE YOU ARE USING MYSOLINE

Things you must do

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

If you go into hospital, please tell medical staff you are taking Mysoline.

Take your Mysoline regularly.

If you do not take it regularly your seizures will not be well controlled.

Things you must not do

Do not stop taking Mysoline, or lower the dosage, without checking with your doctor.

Suddenly stopping Mysoline may cause fits or a withdrawal reaction.

Things to be careful of

Be careful driving or operating machinery until you know how Mysoline affects you.

Mysoline can make some people sleepy and it may take you longer to react in certain situations. Make sure you know how you react to Mysoline before you do anything that could be dangerous if you may need to react quickly.

Be careful when drinking alcohol while you are using Mysoline.

Mysoline may increase the effects of alcohol.

Taking Mysoline 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

Please talk to your doctor or pharmacist about these things if you think they may bother you.

SIDE EFFECTS

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

Mysoline helps most people with seizures, but it may have unwanted side effects in some people.

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 side effects.

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

Tell your doctor if you notice any of the following and they worry you:

- drowsiness
- tiredness
- headache
- nausea or vomiting
- visual disturbances
- dizziness or unsteadiness when walking

These things may happen when you first take Mysoline but usually go away after a while.

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

- 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
- worsening of your epilepsy symptoms
- worsening or blistering rash

Tell your doctor immediately or go to Accident and Emergency at

your nearest hospital if any of the following happen:

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

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

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

Some people may get other side effects while taking Mysoline.

Long term effects

Mysoline 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 Mysoline, your doctor may decide to monitor your bone density and suggest supplements to assist with your bone health.

AFTER USING IT

Storage

Keep your Mysoline tablets in the bottle until it is time to take them.

If you take Mysoline out of the bottle it will not keep well.

Keep it in a cool dry place where the temperature stays below 25°C.

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

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where young 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

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

PRODUCT DESCRIPTION

What Mysoline looks like

Mysoline tablets are white, or virtually white, round biconvex, uncoated tablets that are plain on one side with a bisecting line on the other side. "M" is printed on either side of the bisecting line.

Ingredients

Each Mysoline tablet contains 250 mg primidone as the active ingredient.

Plus:

- povidone
- carmellose calcium
- gelatin (E441)
- magnesium stearate (E572)
- stearic acid (E570)

Distributed in Australia by:

Link Medical Products Pty Ltd
5 Apollo Street
Warriewood, NSW 2102
AUSTRALIA

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See TGA website (www.tga.gov.au) for latest Australian Consumer Medicine Information.