

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using MYSOLINE?

MYSOLINE contains the active ingredient Primidone. MYSOLINE is used to control epilepsy.

For more information, see Section [1. Why am I using MYSOLINE?](#) in the full CMI.

### 2. What should I know before I use MYSOLINE?

Do not use MYSOLINE if you have ever had an allergic reaction to Primidone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MYSOLINE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may be affected by MYSOLINE or may affect how well MYSOLINE works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use MYSOLINE?

- Your doctor or pharmacist will tell you how many tablets you will need to take each day
- Follow the instructions provided and use MYSOLINE until your doctor tells you to stop

More instructions can be found in Section [4. How do I use MYSOLINE?](#) in the full CMI.

### 5. What should I know while using MYSOLINE?

Things you should do	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using MYSOLINE</li><li>• Take your MYSOLINE regularly</li><li>• Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>• Do not stop taking MYSOLINE, or lower change the dosage, without checking with your doctor</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how MYSOLINE affects you</li></ul>
Drinking alcohol	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while you are using MYSOLINE as it may increase the effects of alcohol</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25 °C</li><li>• Keep your MYSOLINE tablets in the bottle until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while using MYSOLINE?](#) in the full CMI.

### 6. Are there any side effects?

MYSOLINE may have unwanted side effects in some people. If you do experience any side effects, most of them are minor and temporary. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MYSOLINE.

If you get any of the following side effects, tell your doctor immediately or go to Accident and Emergency at your nearest hospital: Rash, itching or hives, swelling of the face, lips, tongue or throat, any thoughts of harming yourself or others, or thoughts of committing suicide.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MYSOLINE®

Active ingredient: *Primidone*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using MYSOLINE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MYSOLINE.**

**Where to find information in this leaflet:**

- [1. Why am I using MYSOLINE?](#)
- [2. What should I know before I use MYSOLINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MYSOLINE?](#)
- [5. What should I know while using MYSOLINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using MYSOLINE?

**MYSOLINE contains the active ingredient primidone.** MYSOLINE 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 is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits).**

**MYSOLINE may also be used for the treatment of other seizures and movement disorders such as partial seizures (Jacksonian seizures), myoclonic (involuntary) jerks and akinetic attacks (sudden loss of muscle tone).**

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

### 2. What should I know before I use MYSOLINE?

#### Warnings

**Do not use MYSOLINE if:**

- you are allergic to primidone or any of the ingredients listed at the end of this leaflet  
Always check the ingredients to make sure you can use this medicine
- you have a rare metabolic disorder called acute intermittent porphyria

**Check with your doctor if you:**

- have any other medical conditions such as liver, problems
- kidney or lung problems
- take any medicines for any other conditions

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

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

MYSOLINE can be harmful to unborn children when taken by a woman during pregnancy. It can cause birth defects and can affect the way in which the child develops as it grows. However, do not stop taking MYSOLINE unless your doctor says so as there are risks to the mother and child from uncontrolled epilepsy.

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 excessively sleepy and difficult to wake, speak to your doctor before breastfeeding again.

### Contraception use

Use an effective method of contraception and consult your doctor before planning pregnancy.

MYSOLINE can seriously harm an unborn child when taken during pregnancy. If you are a female of childbearing age, you must use at least one highly effective method of contraception (such as an intra-uterine device) or two complementary forms of contraception including a barrier method should be used, without interruption during your entire treatment with MYSOLINE and for two months after stopping treatment.

Your doctor should discuss with you the most appropriate method of contraception for you.

MYSOLINE may result in a failure of the oral contraceptive pill, you should let your doctor know that you are taking it.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MYSOLINE.**

## 4. How do I use MYSOLINE?

### How much to take

- your doctor or pharmacist will tell you how many tablets you will need to take each day. Your dose will be adjusted according to your response
- follow the instructions provided and use MYSOLINE until your doctor tells you to stop

### When to take MYSOLINE

- MYSOLINE is usually taken twice a day
- MYSOLINE should be used regularly at the same time each day
- if you have trouble remembering when to take your medicine, ask your pharmacist for some hints

### If you forget to use MYSOLINE

- MYSOLINE should be used at the same times each day.
- **if you miss your dose at the usual time, 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 your next dose, skip the dose you missed and take your next dose when you are meant to. Then go back to taking it as you would normally
- **do not take a double dose to make up for the dose you missed**

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

### If you use too much MYSOLINE

If you think that you or anyone else have taken too much MYSOLINE, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor or pharmacist, or
- go to the Emergency Department at your nearest hospital

**You should do this even if there are no signs of discomfort or poisoning.**

If you take too many MYSOLINE tablets you might feel unsteady and drowsy. You may lose consciousness.

## 5. What should I know while using MYSOLINE?

### Things you must do

Tell any other doctor, dentist, or pharmacist you visit that you are taking MYSOLINE.

#### 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**

### Things you should not do

- **do not stop taking MYSOLINE, or change the dosage, without checking with your doctor**

Suddenly stopping MYSOLINE may cause fits or a withdrawal reaction.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how MYSOLINE affects you.**

MYSOLINE can make some people sleepy, and it may take you longer to react in certain situations.

### Drinking alcohol

Be careful when drinking alcohol while you are using MYSOLINE.

MYSOLINE may increase the effects of alcohol.

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

### Looking after your medicine

- **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
- **store below 25 °C**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight where the temperature stays below 25 °C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Your doctor may perform regular tests or other observations to check for changes to your blood levels (anaemia, thrombocytopenia), vitamin D levels, and bone mineral density.

### Less serious side effects

Less serious side effects	What to do
<b>Gut and digestion:</b> <ul style="list-style-type: none"><li>nausea or vomiting</li></ul> <b>Other:</b> <ul style="list-style-type: none"><li>drowsiness or tiredness</li><li>dizziness or unsteadiness when walking</li><li>headache</li><li>visual disturbances</li><li>painful joints</li><li>worsening of your epilepsy symptoms</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Signs of an allergic reaction such as:</b> <ul style="list-style-type: none"><li>rash, itching or hives</li><li>swelling of the face, lips, tongue or throat</li></ul> <b>Signs of liver problems such as:</b> <ul style="list-style-type: none"><li>yellowing of the skin and/or eyes</li></ul> <b>Signs of unusual bleeding such as:</b> <ul style="list-style-type: none"><li>bleeding or bruising under the skin</li></ul> <b>Mental health related:</b> <ul style="list-style-type: none"><li>thoughts or talk about suicide or violence</li><li>thoughts or talk about self-harm or doing harm to others</li><li>attempts at self-harm</li><li>increase in aggressive behaviour, irritability or agitation</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

Serious side effects	What to do
<ul style="list-style-type: none"><li>unusual changes in moods</li><li>worsening of depression</li></ul> <b>Skin:</b> <ul style="list-style-type: none"><li>worsening or blistering rash</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

MYSOLINE is only available with a doctor's prescription.

### What MYSOLINE contains

<b>Active ingredient (main ingredient)</b>	primidone
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>povidone</li><li>carmellose calcium</li><li>gelatin (E441)</li><li>magnesium stearate (E572)</li><li>stearic acid (E570)</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### 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. (Aust R 11231).

### Who distributes MYSOLINE

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

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