PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MYSOLINE 250 mg tablets

Primidone

Read all of this leaflet carefully before you start taking MYSOLINE

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

MYSOLINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT MYSOLINE TABLETS CONTAINS

The active substance is primidone. Each **MYSOLINE** tablet contains 250 mg of primidone

The other ingredients are: carboxymethyl-cellulose calcium, gelatine, magnesium stearate, povidone, and stearic acid.

Sugar free

2. WHAT MYSOLINE TABLETS IS USED FOR

MYSOLINE is an anticonvulsant. **MYSOLINE** is for the treatment of certain types of epilepsy, seizures (fits) or shaking attacks.

3. BEFORE YOU TAKE MYSOLINE TABLETS

Do not take MYSOLINE Tablets

- If you are hypersensitive (allergic) to primidone or any of the other ingredients in **MYSOLINE**, or a substance called phenobarbitone.
- If you have been told that you have porphyria or anyone in your family has it.
- If you suffer from severe liver, kidney or respiratory impairment.
- If you are pregnant or breastfeeding (see section *Pregnancy and Breastfeeding*)

Take special care with MYSOLINE Tablets

- If at any time you have thoughts of harming or killing yourself, immediately contact your doctor.

and tell your doctor:

- if you ever had problems with your breathing, kidneys or liver
- if you are under 18 years of age, an elderly or debilitated patient

as **MYSOLINE** should be given with caution and a reduced dosage may be required.

- if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids. Check with your doctor or pharmacist as there have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures.

Pregnancy and breastfeeding

If you are pregnant, trying to become pregnant or are breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **MYSOLINE**.

MYSOLINE has the potential to harm the unborn child.

MYSOLINE should not be used if you are breastfeeding. Prior to taking any medicine, please inform your doctor or pharmacist that you are breastfeeding.

Driving and using machinery

MYSOLINE can make you feel very sleepy. If so, do not drive or operate machinery.

Taking other medicines with MYSOLINE

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

MYSOLINE may affect or be affected by many other medicines.

It is particularly important to let your doctor know about other anticonvulsants such as phenytoin, or anticoagulants such as warfarin (to prevent blood clots), oral contraceptives (the pill), barbiturates (sleeping tablets), or herbal remedies containing St John's Wort.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines even those not prescribed.

4. HOW TO TAKE MYSOLINE TABLETS

Do not share medicines prescribed for you with any other person.

Always take **MYSOLINE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of **MYSOLINE** is too strong or too weak, talk to your doctor or pharmacist.

At first, your dose may be as little as half a tablet. This will be adjusted by your doctor until your condition is controlled. It may be up to six tablets daily.

Swallow the tablets whole with a drink of water.

MYSOLINE is normally taken twice a day.

Try to take your tablets at the same time each day.

Do not stop taking your tablets even if you are feeling well unless your doctor tells you. Then only do so gradually.

If you take more MYSOLINE Tablets than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Signs of taking too much **MYSOLINE** are increased sleepiness, loss of consciousness, and difficulty in breathing.

If you missed a dose of MYSOLINE

If you miss a dose, take the dose as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

MYSOLINE can have side effects. Not all side effects reported for **MYSOLINE** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MYSOLINE**, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately if you have thoughts of harming or killing yourself. See also *Take special care with **MYSOLINE** Tablets*.

Contact your doctor promptly if the following happens to you, as you may need urgent treatment:

- Severe skin reactions affecting large portions of your body including redness, pain, ulcers, blisters, skin sloughing or involvement of lips and mucous membranes (e.g. toxic epidermal necrolysis, Stevens Johnson syndrome.)

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

- Joint or bone pains, especially during long-term treatment with **MYSOLINE**
- Changes in mood or behaviour
- Development of Dupuytren's contracture (a thickening of fibrous tissue in the palm of the hand that prevents one or more of the fingers from being straightened.)
- Bone disorders including osteopenia and osteoporosis (thinning of the bone), fractures
- Skin rash
- When taking **MYSOLINE** you may feel drowsy and listless

Other events which may occur includes:

- Jerky movements
- Rolling of the eyes
- Disturbances of vision
- Nausea (feeling sick) and vomiting
- Headache
- Dizziness

The following side effects may be seen when a blood test is taken:

- Anaemia (too few red blood cells in the bloodstream resulting in insufficient oxygen to tissue and organs)
- Elevations of liver enzymes

If you have any of these side effects quite severely, consult your doctor straight away.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF MYSOLINE TABLETS

- Store all medicines out of reach of children.
- You should keep your tablets at or below 25 °C, protected from moisture.
- Keep your tablets in the container it came in. Keep the container tightly closed.
- If your doctor decides to stop your treatment, return any left-over tablets to your pharmacist.
- You should not take the tablets after the expiry date on the container. Return all expired medicines to your pharmacist.

7. PRESENTATION OF MYSOLINE TABLETS

MYSOLINE tablets are packed in a white HDPE bottle with a polypropylene (PP) child resistant closure a or a blister-pack containing 100 tablets.

8. IDENTIFICATION OF MYSOLINE TABLETS

MYSOLINE tablets are round, white to almost white, biconvex, uncoated tablets, bisected on one side with 'M' impressed on either side of the breakline.

9. REGISTRATION NUMBER

B/2.5/572

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Acino Pharma (Pty) Ltd

106 16th Road

MIDRAND

11. DATE OF PUBLICATION

Date of registration: 05 September 1978

Date of the most recently revised professional information as approved by regulatory authority:

03 October 2014