LUNALINE TABLET

Maprotiline hydrochloride (25mg, 50mg)

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What LUNALINE is used for

LUNALINE is used to treat depression.

Your doctor may have prescribed LUNALINE for another reason. Ask your doctor if you have any questions about why LUNALINE has been prescribed for you.

How LUNALINE works

LUNALINE contains Maprotiline hydrochloride. It belongs to a group of medicines known as tetracyclic antidepressant.

LUNALINE works by increasing the activity of certain chemicals in the brain (e.g. noradrenaline, serotonin), which help improve mood.

Before you use LUNALINE

When you must not use it

Do not take this medicine if you are allergic to

- Maprotiline hydrochloride
- any of the ingredients listed at the end of this leaflet
- any tricyclic antidepressant

Do not take LUNALINE if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days.

Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.

Do not take LUNALINE if you have recently had a heart attack or you have a history of seizures.

Do not use 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.

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

Before you start to use it

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

Tell your doctor if you are pregnant, plan to become pregnant or breast-feeding. Your doctor will discuss with you the risks and benefits involved.

Tell your doctor if you have or have had any medical conditions, including:

- Heart problems, especially an irregular heart beat
- Glaucoma (high pressure in the eye)
- Increased intraocular pressure
- Impaired liver function
- Impaired kidney function

- Mental disorder other than depression
- Seizures (fits)
- Difficulty in passing urine
- Hyperthyroidism (a condition in which the thyroid gland makes too much thyroid hormone)

If you have not told your doctor about any of the above, tell him/her before you start taking LUNALINE.

- 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 and LUNALINE may interfere with each other. These include:

- Monoamine oxidase inhibitors (e.g. phenelzine)
- Other medicine for depression
- Antipsychotic medicines
- Medicines used to control fits such as phenytoin and carbamazepine
- Benzodiazepines
- Beta blocker eg. propranolol
- Anticholinergic medicines, which are used to relieve stomach cramps

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

If you not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use LUNALINE

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

These directions may differ from the information contained in this leaflet.

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

- How much to use

Adult:

Take 25mg to 75mg daily, in three divided doses. If necessary, gradually increased to a maximum of 150mg daily.

Elderly:

Your doctor will probably start with a low dose (e.g. 10mg three times daily or 30mg at night).

When to use it

If the tablets make you sleepy, your doctor may suggest that you take one dose at night to help you sleep well.

- How long to use it

Continue taking LUNALINE for as long as your doctor recommends.

- If you forget to use it

If it is almost time for 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 tablets as you would normally.

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

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

- <u>If you use too much</u> (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much LUNALINE tablet.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdosage:

- Convulsion (seizures)
- Irregular heartbeat

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking LUNALINE.

If you become pregnant while you are taking LUNALINE tell your doctor immediately. Your doctor will discuss with you the risks and benefits involved.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking LUNALINE.

Things you must not do

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

Do not take LUNALINE 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.

- Things to be careful of

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

LUNALINE may cause drowsiness in some people.

Side effects

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

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

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

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

- Nausea, vomiting
- Upset stomach
- Dry mouth
- Drowsiness, weakness
- Blurred vision

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of LUNALINE

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a 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 it 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.

- <u>Disposal</u>

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. These measure will help to protect the environment.

Product Description

- What it looks like

LUNALINE TABLET 25MG

A pink colour, 7mm round tablet with 'd' and 'd' markings.

LUNALINE TABLET 50MG

A blue colour, 7mm round tablet with 'd' and 'd' markings.

- <u>Ingredients</u> Active ingredient:

LUNALINE TABLET 25MG

Each tablet contains 25mg maprotiline hydrochloride

LUNALINE TABLET 50MG

Each tablet contains 50mg maprotiline hydrochloride

Inactive ingredients:

LUNALINE TABLET 25MG

- Aerosil
- Promigel
- Carmoisine
- Cornstarch
- Polyvinyl pyrollidone
- Lactose
- Magnesium stearate

LUNALINE TABLET 50MG

- Aerosil
- Promigel
- Brilliant blue
- Cornstarch
- Polyvinyl pyrollidone
- Lactose
- Magnesium stearate

- <u>MAL number</u>

LUNALINE TABLET 25MG MAL19950285A

LUNALINE TABLET 50MG MAL19950286A

Manufacturer

DUOPHARMA (M) SDN. BHD. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder DUOPHARMA (M) SDN. BHD. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

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