

THE DISPENSING OF THE MEDICINE REQUIRES A DOCTOR'S PRESCRIPTION

PRYSOLINE TABLETS

Composition:

Active Ingredient: Primidone 250 mg

Inactive ingredient: see the chapter 6- further information

Read this package insert carefully in its entirety before using this medicine.

This leaflet contains essential information of this medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

1. For what is intended this medicine?

Anticonvulsant.

Therapeutic group: antiepileptic.

2. Before use this medicine:

Do not take this medicine if: Do not use this medicine if you are sensitive to any of its ingredients or to any medicine of the barbiturates group as Phenobarbital. Do not use this medicine in case of porphyria or if you have a history of the disease or if someone in your family suffer from this disease.

Do not take this medicine without consulting a doctor before starting treatment:

- If you are pregnant or you are trying to become pregnant or breast-feeding (see pregnancy and breast-feeding chapter).
- If you are suffering, or have suffered in the past, from impaired function of: respiratory system, the liver, the kidney/urinary tract.
- If you are suffering or have suffered in the past from depression, mood disturbance, suicidal behaviors or thoughts.

Special warning concerning the medicine drug: Prolonged use may cause dependence. If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine. This medication contradicts the activity of contraceptive pills; therefore, the attending doctor should be informed. Elderly patients are usually more sensitive to the effects of this medicine. Inform your doctor that you are taking this medicine before undergoing any medical examinations or having any kind of surgery (including dental surgery) or emergency treatment. A small number of people being treated with anti-epileptics such as primidone have had thoughts of harming or killing themselves. The patients or their family members are advised to pay attention to behavior changes. If such change occurs, refer to the doctor immediately. The medical follow up is important with this medicine treatment, especially in patient with history of suicide attempt, depression and mood disturbance.

If you are taking another medicine or if you have just finished treatment with another medicine included over the counter drug and food additive, inform the attending doctor or pharmacist in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups:

- Drugs affecting the central nervous system: sedatives, hypnotics, drugs for parkinsonism, drugs for epilepsy, antihistaminic preparations.
- Other medicines used to treat epilepsy (such as phenytoin, felbamate, sodium valproate, carbamazepine, ethosuximide, oxcarbazepine, tiagabine, topiramate, zonisamide).
- Antidepressant (tricyclic antidepressants, lamotrigine, mianserin).
- Barbiturates (such as sleeping tablets).
- Medicines used to treat high blood pressure or heart conditions (such as beta-blockers, digoxin, losartan, nifedipine, quinidine).
- Asthma medicines (such as theophylline, montelukast).
- Hormone containing medicines (such as the oral contraceptive pill).
- Methadone (used as a substitute for morphine addition and to treat severe pain).
- Antibiotics (such as chloramphenicol, metronidazole, doxycycline)
- Antiviral medicines (such as nefirnavir).
- Cyclosporin (used to prevent rejection of an organ transplant and for other immune system diseases).
- Medicines used to treat cancer (such as cyclophosphamide, etoposide).
- Granisetron (medicine to treat nausea and vomiting).
- Surgical anesthesia drugs (such as rocuronium, vecuronium).
- Medicines containing morphine or others opioids medicines.
- Anticoagulant medicines (such as warfarin).
- Medicines containing steroids.
- Medicines from Hypericum plant (St John's Wort for treating depression).

This medicine, Prysoline, may increase the toxic effect on the liver of an overdose of paracetamol.

Pregnancy and breast-feeding: Do not take this medicine without consulting a doctor before starting treatment if you are pregnant or breast-feeding.

Pregnancy: The use of this medicine may harm the normal development of fetus. You must tell your doctor if you are pregnant, or trying to become pregnant because this medicine may harm the fetus. The use of this medicine during the pregnancy may reduce the quantity of folic acid in blood's patient. In addition, the baby may develop the withdrawal symptoms due to the use of this medicine during the late stages of pregnancy. Blood clotting problems have occurred occasionally in children born to women who were previously taking anticonvulsant drugs.

Breast-feeding: If you are breast-feeding The use of this medicine may cause sleepiness and drowsiness of the baby.

Driving and using machines: Use of this medicine may impair alertness and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery and in any other activity which requires alertness. Children should be cautioned against engaging in activities such as bicycle riding, playing near roads and the like. Do not drive or operate machinery during the use of this medicine before make sure you are not affected by this medicine.

Do not drink wine or alcoholic beverages while under treatment with this medicine.

3. How use this medicine?

Always take this medicine exactly as doctor's instruction. Do not exceed the recommended dosage. This medicine is to be taken at specific time intervals as determined by the attending doctor.

The treatment should be consistent as recommended by the attending doctor. Do not stop taking this medicine, even if you are feeling well, unless your doctor tells you. This medicine may cause dependence; therefore you could get a withdrawal reaction if you stop treatment too quickly. You must stop the treatment gradually according to your doctor's recommendation. Do not chew! Swallow the medicine with water. Do not take this medicine with alcohol.

It is recommended to take this medicine with food or milk.

The tablet may be halved/ crushed.

If you forget to take this medicine, take the dose as soon as you remember, but never take a double dose. Take the next dose at your regular time and consult with the doctor.

If you have taken an overdose or if a child has accidentally swallowed the medicine, contact immediately the doctor or proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Possible overdose signs: depression of central nervous system including lack of muscle control (ataxia), loss of consciousness, respiratory depression and coma. If you have any further questions on the use of this product, consult your doctor or pharmacist.

4. Side Effects:

Like all medicines, some patient may develop side effects after using. Do not be alarmed by this list of side effects. You may not have any of them.

Special side effects: Stop the treatment and consult immediately the doctor in event of severe allergic reaction: Skin reactions affecting large portions of your body including redness, pain, ulcers, blisters, shedding the outer layer of skin or involvement of lips, the oral cavity, nostrils or ears, urticaria, dyspnea, hyperhidrosis, blush, swelling, especially of the face and the throat, fainting stop the treatment and call immediately medical help. In commencing of treatment it is possible to occur side effects such as drowsiness and lack of energy. These side effects usually disappear within a short time following the period of adaptation to the medicine.

Common side effects (affecting fewer than 1 in every 10 people):

Disturbances of vision, dizziness, jerky movements, rolling of the eyes, problems in walking and movement.

Uncommon side effects (affecting fewer than 1 in every 100 people):

Nausea and vomiting, headache, skin rash.

Consult immediately the doctor in next events:

Rare side effects (affecting fewer than 1 in every 1000 people):

- Changes in mood or behavior.
- Joint or bone pain.
- Raised levels of enzymes in the liver.
- Development of disease named "Dupuytren's contracture" (a thickening of fibrous tissue in the palm of the hand that causes one or more fingers to draw back).
- A disease called lupus erythematosus (autoimmune disease which causes inflammation of various parts of the body including the skin, joints, lungs, kidneys, heart, and liver). Symptoms including generally: fatigue, tiredness, fever, pain and swelling of joints, "butterfly rash" on the face that spreads over the bridge of the nose and across the cheeks.
- Abnormalities of the blood cells; if you notice a pale appearance of your skin, abnormal bleeding or tendency to bruising; fever or sore throat please consult your doctor.

If a side effect exacerbates or that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Adverse reactions and drug interaction in children: Parent must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child. See above for the details of side effects and drug interactions.

5. How to store this medicine?

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them. Do not use this medicine after (expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.)

Store below 25°C in a dry place.

6. Further information:

In addition of active ingredient (substance) this medicine contains also:

C.M.C. Calcium, Starch, Gelatine, PVP K-30, Magnesium Stearate, Stearic Acid.

Holder and manufacturer: Rekah Pharmaceutical Prod. Ltd., 30 Hamelacha St., Holon

This leaflet was checked and approved it in 04/2012

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For simplicity and easier to read, this leaflet is formulated male language, however, the medicines is intended for members of both sex.