

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
THE DISPENSING OF THE MEDICINE REQUIRES A DOCTOR'S PRESCRIPTION

PHENOBARBITONE

15 mg and 100 mg

TABLETS

This format of this leaflet was determined by the ministry of Health
and its content was checked and approved it in June 2013

Active Ingredient: Phenobarbitone 15 mg or 100 mg
Inactive ingredient: see the chapter 6- furthers 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?

Phenobarbitone is a barbiturate which acts as a sedative and hypnotic in short-term treatment of insomnia.

Therapeutic group: Phenobarbitone belongs to the barbiturates group.

2. Before use this medicine:

Do not take this medicine:

- Do not use this medicine if you are sensitive to phenobarbitone or any medicine of the barbiturates group or any of its ingredients.
- Do not use this medicine if you suffering, have suffered in past from porphyria (a genetic or inherited disorder of the red blood pigment, haemoglobin) or if someone in your family suffer from this disease.
- Do not use this medicine if you are suffering from a severe disease of the live, or the kidney, severe breathing difficulties.

If you develop a rash or the following skin symptoms, seek immediate advice from a doctor and tell that you are taking this medicine:

- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Phenobarbitone tablets. appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Phenobarbitone tablets you do not take this medicine.

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

- If you are or have been dependent on drugs, medications or alcohol.
- If you are suffering, or have suffered in the past, from impaired function of: respiratory system (Breathing difficulties), the liver, the kidney/urinary tract, from acute or chronic pain, or if you are elderly, run down, you are suffer from dementia (senile).
- 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 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. 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.

Do not use this medicine frequently or for a prolonged period without consulting a doctor.

A small number of people being treated with the phenobarbitone have had thoughts of harming or killing themselves. It's recommended that 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.

This medicine is against the activity of oral contraceptives to prevent pregnancy, therefore inform you doctor.

If you are taking another medicine or if you have just finished treatment with another medicine included over the counter drugs and dietary additives, inform the attending doctor or pharmacist in order to prevent hazards or lack of efficacy arising from drug interactions.
Specially, inform your doctor or pharmacist if you take:

- Quinidine and disopyramide (to treat irregular heartbeats).
- Medicine to treat infection (such as chloramphenicol, metronidazole, doxycycline, rifampicin, telithromycin, griseofulvin, itroconazole, posaconazole, voriconazole).
- Antiviral medicines (such as nelfinavir, abacavir, amprenavir, lopinavir, indinavir, daranavir, saquinavir).
- Warfarin (medicines used to thin the blood).
- Antidepressant (tricyclic antidepressants, medicine from MAO inhibitor, paroxetine, mianserin).
- Medicines from Hypericum plant (St John's Wort for treating depression).
- Medicines used to treat epilepsy (such as phenytoin, sodium valproate, primidone, carbamazepine, ethosuximide, oxcarbazepine, tiagabine, topiramate, zonisamide, lamotrigine, vigabatrin).
- Chlorpromazine, thioridazine, haloperidol, aripiprazole and clonazepam (to treat mental illness).
- Medicines used to treat high blood pressure: felodipine, verapamil, diltiazem, nifedipine, nimodipine, beta-blockers such as metoprolol, timolol and propranolol.
- Medicines used to treat certain heart conditions (such as digoxin or eplerenone).
- Cyclosporin or tacrolimus (used to prevent rejection of an organ transplant for other immune system diseases).
 - Steroids (such as hydrocortisone or prednisolone).
 - Dietary supplements: Folic acid and vitamin D.
 - Medicines used to treat cancer (such as irinotecan, gestrinone, toremifene, etoposide).
 - Methadone (used as a substitute for drugs addiction and to treat severe pain).
 - Oral contraceptive pill (consult your doctor about the best method of contraception for you), tibolone (female hormone).
 - Thyroid hormone: levothyroxine.
 - Asthma medicines (such as theophylline, montelukast).
- Tropisetron and aprepitant (to treat nausea and vomiting).
- Memantine (to treat dementia).
- Methylphenidate (to treat attention deficit disorder).
- Sodium oxybate (to treat narcolepsy).

Use of this medicine and food: Do not chew! Swallow the medicine with water.

Use of this medicine and alcohol beverage: Do not drink wine or any other alcoholic beverages while using the medicine.

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

This medicine impairs the effectiveness of oral contraceptives; therefore, when using this medicine you should use an additional contraceptive method.

Pregnancy: You must inform your doctor if you are pregnant, or trying

to become pregnant because this medicine may harm the fetus. The use of this medicine may harm the normal development of fetus. If you take phenobarbitone with folic acid supplement, consult your doctor in order to adjust the dosage.

Breast-feeding: Do not breast-feed if you use this medicine.

Do not use this medicine if you are breast-feeding.

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.

Important information on the Phenobarbitone tablets composition: Each tablet of phenobarbitone 15 mg contains 31 mg of lactose and each tablet of phenobarbitone 100 mg contains 1.5 mg of lactose. Do not use if you are allergy to the lactose. Phenobarbitone 100 mg tablet contains preservatives. This medicine may cause allergic reactions. Phenobarbitone 15 mg tablet contains sucrose. If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How use this medicine?

Always take this medicine exactly as doctor's instruction. **If you are unsure how to use this medicine you should check with the doctor or the pharmacist.** The dosage and treatment are determined by the doctor only.

Do not exceed the recommended dosage. This medicine is to be taken at specific time intervals as determined by the attending doctor. Do not chew! Swallow the medicine with water. Do not take this medicine with alcohol. The tablet may be halved/ crushed.

Test: Phenobarbitone tablets may interfere with the results of blood or urine test. If you need this test, inform the medical team that you take this medicine.

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: drowsiness, speech problems, jerky movements, jerky eye movements, loss of inhibition, reduced reflex response, low body temperature, low blood pressure and breathing problems.

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.

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 (such as sleeplessness, anxiety, tremor, dizziness, feeling sick, fits and delirium) if you stop treatment too quickly. You must stop the treatment gradually according to your doctor's recommendation.

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. • The treatment should be consistent as recommended by your attending doctor. • If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. Side Effects:

As with any medicine, use phenobarbitone may cause side effects in some of users. Do not be alarmed by this list of side effects. You may not experience any of them.

- **Allergic reaction:** skin rash, fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.
- **Blood:** altered numbers and types of blood cells (agranulocytosis, reduction of platelet number (thrombocytopenia) and anemia); consult your doctor if you notice increased bruising, nosebleeds, sore throats or infections.
- **Metabolism and nutrition:** bone softening and bone disease. There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.
- **Mental health:** restlessness and confusion in the elderly, unusual excitement, depression, memory impairment, hallucinations.
- **Nervous system:** hyperactivity, behavioral disturbances in children, jerky movements, jerky eye movements, lethargy , drowsiness.
- **Heart:** low blood pressure.
- **Lungs:** difficulty breathing.
- **Liver:** inflammation of the liver (hepatitis), damaged bile system (cholestasis). Signs: yellowing of skin and whites of eyes.
- **Kidneys:** changes in the amount or need to pass water.
- **Skin:** rashes, erythema multiforme (circular, irregular red patches), lumps in the armpits or groin area.

Consult immediately the doctor in next events:

Potentially life-threatening skin rashes (rare) such:

- **Stevens-Johnson syndrome:** severe potentially life-threatening skin rash with flushing, fever, blisters or ulcers.

- **Toxic epidermal necrolysis:** severe rash involving reddening, peeling and swelling of the skin that resembles severe burns.

These rashes initially manifest in red spots or rounded patches with blister in the center. Other signs to watch out for are ulcers in the mouth, throat, nose, genital and eye inflammation (red, swollen eyes). These two rashes are life-threatening and can be accompanied by symptoms similar to influenza. Blistering rash can worsen simplified or peeling of the skin.

Highest risk of developing a dangerous skin reaction actually existed in the first weeks treatment.

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 interactions 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 use this medicine after the expiry date stated on the label/ carton/bottle.
- The expiry date refers to the last day of that month.
- Store below 25°C and in a dry and dark place. Keep away from light.

6. Further information:

In addition of active ingredient (substance) this medicine contains also: Phenobarbitone 15 mg: Corn starch, lactose, talc, sucrose, gelatin, magnesium stearate.

Phenobarbitone 100 mg: Starch, Talc, Ac-di-sol, Lactose, C.M.C. sodium, Microcrystalline cellulose, Magnesium stearate, Acacia, Aerosil 200, methyl paraben sodium.

What does the medicine look like and what is the content of the package:

Phenobarbitone 15 mg: White tablet, REKAH engraved on one side, plain on the other

Phenobarbitone 100 mg: White tablet, R engraved on one side, plain on the other.

Holder and manufacture: Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St. Holon, Israel.

This leaflet was checked and approved it in 06/2013

Registration number of this medicine in drug list of health ministry:

Phenobarbitone 15 mg: 028 45 21937 00

Phenobarbitone 100 mg: 028 67 21938 00

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