

Gardenal® 10 mg Gardenal® 100 mg

phenobarbital

tablets

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or are unsure of anything, ask your doctor or pharmacist for more information.
- 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.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Gardenal 10 mg/100 mg tablets are and what they are used for
2. Before you take Gardenal 10 mg/100 mg tablets
3. How to take Gardenal 10 mg/100 mg tablets
4. Possible side effects
5. How to store Gardenal 10 mg/100 mg tablets
6. Further information

1. WHAT Gardenal 10 mg/100 mg tablets ARE AND WHAT THEY ARE USED FOR

ANTI-EPILEPTIC

This medicine is recommended for the treatment of certain types of epilepsy in adults and children.

2. Before you take Gardenal 10mg/100mg tablets

Never take Gardenal 10 mg/100 mg tablets in the following situations:

- certain blood disorders
- known allergy to phenobarbital or to other medicines of the barbiturate class
- serious respiratory problems
- in combination with saquinavir (an antiviral agent), ifosfamide (an anticancer agent), voriconazole or St. John's Wort
- if you are allergic (hypersensitive) to wheat, as this medicine contains wheat starch.

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with Gardenal 10 mg/100 mg tablets:

Special warnings

This medicine is not effective in some types of epilepsy. If the frequency of seizures increases or if seizures of a different type occur, CONSULT YOUR DOCTOR IMMEDIATELY. Do not stop treatment abruptly, as this may cause the recurrence of seizures.

Self-destructive or suicidal thoughts have also occurred in a small number of people treated with anti-epileptic medication such as Gardenal. If these types of thoughts occur, contact your doctor immediately.

You may take this medicine if you have celiac disease. Wheat starch can contain gluten, but only traces, and is

therefore considered safe for patients with celiac disease.

Precautions for use

You are strongly advised not to consume alcohol while taking this medicine.

Regular monitoring by your doctor is required. Treatment should be stopped if generalized allergic reactions, skin rash, or liver function disorders occur.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

TAKE SPECIAL CARE with this medicine in the following situations:

- liver disease,
- kidney disease,
- respiratory problems.

If you have to be hospitalized, the medical staff must be informed that you are taking this medication.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking/using other medicines

Tell your doctor if you are taking a contraceptive, and also if you are already using anticoagulants, anticonvulsants, anti-infectives, anticancer drugs or other medicines which have an effect on the nervous system (tranquillizers, antidepressants) or medicines containing alcohol.

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Food and drink

Avoid drinking any alcoholic beverages.

Pregnancy and breast-feeding

Pregnancy

Inform your doctor as soon as possible if you are pregnant or wish to become pregnant.

Your doctor will decide whether you should pursue treatment and may implement special monitoring based on your case and the treatment you are receiving.

Breast-feeding

Breast-feeding is not recommended during treatment.

Tell your doctor as soon as possible if you are breast-feeding or wish to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Because of the risk of drowsiness, take special care if you drive vehicles or operate machines.

List of excipients with specific effects

Wheat starch.

3. HOW TO TAKE GARDENAL 10mg/100mg, tablets

Dosage

The dosage will be determined by your doctor and then gradually adjusted. It is strictly individual.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

Method of administration

Oral use. The tablets should be crushed and mixed with food before being given to children under 6 years of age.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

Frequency of administration

Children should have one or two doses.

Adults should have only one dose per day in the evening at bedtime.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

Duration of treatment

Do not change the dosage or stop treatment without medical advice.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

If you take more Gardenal 10 mg/100 mg, tablets than you should:

Inform your doctor or hospital.

If you forget to take Gardenal 10 mg/100 mg, tablets:

If you forget to take a dose, take it as soon as you realize you have forgotten it, but if you remember when it is time for the next dose, do not take two doses.

Then continue as before.

If you stop taking Gardenal 10 mg/100 mg, tablets:

Treatment must be stopped gradually; sudden discontinuation of treatment (or major reduction in dose) may cause seizures to reappear.

4. Possible side effects

Like all medicines, Gardenal 10 mg/100 mg, tablets can cause side effects, although not all patients have them.

- drowsiness in the morning
- waking difficulties, sometimes with slurring of speech
- coordination and balance problems
- rarely, dizziness with headaches
- skin rash and serious skin disorders
- impaired liver function, rare cases of hepatitis
- generalized allergic reaction: fever, skin rash, liver function disorders
- joint pain (shoulder-hand syndrome or gardenal-induced rheumatism)
- mood disorders
- blood abnormalities (megaloblastic anemia due to folic acid deficiency)
- dependence if treatment is taken for a long period of time
- retraction of fascia in the palm (Dupuytren's disease), or in the sole of the foot (Ledderhose's disease) and hardening of the spongy tissue of the penis (Peyronie's disease).

Treatment should be discontinued if generalized allergic reactions, skin rash, or liver function disorders occur.

If you notice any side effects not mentioned in this leaflet, or if any of the side effects gets serious, please inform your doctor or pharmacist.

5. HOW TO STORE Gardenal 10mg/100mg tablets

Keep out of the reach and sight of children.

Do not use Gardenal 10 mg/100 mg tablets after the expiry date printed on the box.

The expiry date refers to the last day of the month.

Store at a temperature no higher than 25°C.

Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist how to dispose of unused medicines. This will help to protect the environment.

6. Further information

What Gardenal 10 mg/100 mg tablets contain

The active substance is:

Phenobarbital..... 10 mg /100 mg
for 1 tablet.

The other ingredients are:

Potato starch, wheat starch, dextrin, magnesium stearate, calcium carbonate

What Gardenal 10 mg/100 mg tablets look like and contents of the pack

This medicine is a tablet.

Gardenal 10 mg: box of 80.

Gardenal 100 mg: box of 20.

Marketing Authorization Holder and Operating Company

sanofi-aventis France

1-13, boulevard Romain Rolland

75014 Paris, France

Manufacturer

FAMAR LYON

29, avenue du Général de Gaulle

69230 Saint Genis Laval - France

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