

## **Fenobarbital 25 mg, 50 mg tablets**

### **What is Fenobarbital and what is it used for?**

Fenobarbital belongs to the group of barbiturates: a certain group of medicines for epilepsy.

Use for epilepsy (falling sickness) with the exception of absences (moments of decreased consciousness).

### **What you need to know before using fenobarbital teva?**

**Potentially** life-threatening skin reactions (Stevens-Johnson syndrome or toxic epidermal necrolysis) have been reported with the use of carbamazepine, and at an early stage, symptoms manifest with high fever, blisters on the skin and/or eye inflammation (Stevens-Johnson syndrome) or with fever and blisters on the skin and shedding of the skin (toxic epidermal necrosis).

Other symptoms to watch out for include ulcers in the mouth, throat, nose, genitals, and conjunctivitis (red and swollen eyes).

This potentially life-threatening skin rash often comes with flu-like symptoms. The rash can spread to many blisters or result in skin detachment. The highest risk of developing skin reactions is during the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis while using phenobarbital, you must not use phenobarbital again under any circumstances. If you develop a rash or other skin reactions, contact your doctor immediately and tell them that you are using this medication.

Do not use Fenobarbital Teva:

- if you are allergic (hypersensitive) to phenobarbital, other barbiturates or any of the other ingredients in Fenobarbital Teva
- if you have acute intermittent porphyria (a certain hereditary metabolic disorder)
- if you have severe respiratory disorders for "overactivity" in children.

Consult your doctor if any of the above warnings apply to you, or have been in the past.

### **Be extra careful with Fenobarbital Teva:**

If you are using St. John's wort and Fenobarbital at the same time, as this can reduce the effectiveness of Fenobarbital Teva. Products containing St. John's wort should not be used together with Fenobarbital Teva. If you are already using St. John's wort, you should contact your doctor. The doctor will usually check the amount of phenobarbital in your blood and advise you to stop using St. John's wort. It is important that you are monitored by your doctor during and after stopping, as stopping St. John's wort can increase the amount of phenobarbital in your blood. This can amplify the effects and side effects of Fenobarbital Teva. In some cases, the dosage of Fenobarbital may need to be adjusted. See also the section 'Use with other medicines'.

If you use phenobarbital for a long period of time, it may lead to tolerance and addiction. Discontinuing the use of this medication should be done gradually by slowly reducing the dosage in consultation with your doctor. Sudden discontinuation can cause severe withdrawal symptoms, such as delusions.

If you have poor liver, kidney or lung function or respiratory disorders, or if you are depressed and/or have suicidal tendencies, or have had them in the past. In all these cases, this medication should be used with extra caution and in low dosages.

If you experience or develop anemia, phenobarbital may cause anemia in exceptional cases. Treatment with phenobarbital should be stopped, and anemia should be treated. Therefore, consult your doctor if you experience anemia symptoms.

A small number of people treated with antiepileptic drugs such as Phenobarbital have had thoughts of self-harm or suicide. If you have such thoughts at any time, contact your doctor immediately.

### **Use with other medicines**

Note: The following comments may also apply to the use of medicines in the past or in the near future.

The medicines mentioned in this section may be known to you by another name, often the brand name. In this section, only the name of the active ingredient or the group of active ingredients of the medicine is mentioned, not the brand name! Therefore, always check the packaging or the package insert to see what the active ingredient is in the medicines you are using.

An interaction means that (medicinal) substances influence each other's effect and/or side effects when used simultaneously. An interaction can occur when using these tablets with: Sleeping pills, Sedatives, Medicines for motion sickness, Medicines for hypersensitivity (antihistamines), Medicines for depression (severe melancholy), Medicines for psychosis (mental illnesses), Other anti-epileptic drugs; this interaction will often be desired by your doctor, Anticoagulant tablets, Oral contraceptives ("the pill"), Strong painkillers (so-called opioids, such as morphine, dextropropoxyphene, pethidine), Verapamil, nifedipine, and felodipine (certain medicines used for high blood pressure or heart conditions (the so-called calcium antagonists, for example, verapamil, nifedipine, and felodipine)), Beta-blockers (certain medicines used for high blood pressure, certain heart conditions, or elevated eye pressure (the so-called beta-blockers, for example, metoprolol, propranolol, and timolol)), Corticosteroids (adrenal cortex hormones with, among other things, an anti-inflammatory effect (for example, prednisone, prednisolone, and dexamethasone)), Chloramphenicol (a medicine for infections), Quinidine (a medicine for arrhythmias), Cyclosporine (a medicine to suppress the immune system, for example, after a transplant or in severe cases of rheumatism), Theophylline (a medicine used to treat shortness of breath), Griseofulvin (a medicine against fungal infections), Chlorpromazine (a medicine used, among other things, in psychoses)

(Plant-based) remedies containing St. John's Wort (*Hypericum perforatum*), a treatment for depression, can reduce the effectiveness of Fenobarbital Teva. Therefore, you should not use St. John's Wort remedies with Fenobarbital Teva. See also the section "Warnings and precautions".

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those that you can get without a prescription.

**Use of Fenobarbital with food and drink:** This medicine and alcohol can enhance each other's effects, so be careful when using alcohol.

#### **Pregnancy and breastfeeding:**

**Pregnancy:** Women of childbearing age/contraception:

If you are a woman of childbearing age, you must use effective contraception during treatment with fenobarbital and for two months after treatment. Fenobarbital can affect the effectiveness of hormonal contraceptives such as the pill and make them less effective in preventing pregnancy. Contact your doctor, who will discuss with you which type of contraception is best to use while taking fenobarbital.

If you are a woman of childbearing age and planning to become pregnant, talk to your doctor before stopping contraception and before becoming pregnant about switching to other suitable treatments to prevent the unborn baby from being exposed to fenobarbital.

If fenobarbital is taken during pregnancy, it can cause serious birth defects and affect the way the child develops during growth.

Birth defects reported in studies include cleft lip (split in the upper lip) and cleft palate (split in the roof of the mouth) and heart defects. Other birth defects have also been reported, such as deformities of the penis (hypospadias), smaller than normal head circumference, abnormalities of the face, nails, and fingers. If you use fenobarbital during pregnancy, you have a higher risk than other women of having a child with birth defects that require medical treatment. In the general population, the baseline risk of serious malformations is 2-3%. This risk is about 3 times higher in women who use fenobarbital.

Babies born to mothers who use fenobarbital during pregnancy may also have an increased risk of being smaller than expected.

Neurological developmental disorders (delays in development due to disturbances in brain development) have been reported in children exposed to fenobarbital during pregnancy. Studies on the risk of neurological developmental disorders remain contradictory.

Phenobarbital should not be used during pregnancy unless nothing else works for you. Contact your doctor immediately if you are pregnant. Your doctor should discuss the potential effects of phenobarbital tablets on the unborn child, and the risks and benefits of treatment should be carefully weighed. Do not stop taking phenobarbital before discussing this with your doctor, as abruptly stopping medication can increase the risk of developing seizures, which can have harmful effects on you and the unborn child.

If you have used phenobarbital during the last third of pregnancy, appropriate monitoring should be done to detect possible conditions in the newborn, such as seizures, excessive crying, muscle weakness, and sucking difficulties.

Phenobarbital can cause a blood clotting disorder in the newborn, which can lead to bleeding. In this case, vitamin K can be given to the mother in the last month of pregnancy. Otherwise, during delivery, 10 mg of vitamin K can be given to the mother and 1 mg to the newborn.

Pregnant patients should have their blood folate levels checked.

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

**Breastfeeding:** Phenobarbital passes into breast milk. When breastfeeding is continued, the baby should be monitored for unwanted effects of phenobarbital, such as unusual drowsiness. Ask your doctor or pharmacist for advice before taking any medication.

**Driving and using machinery:** This medicine can adversely affect your reaction time. Therefore, be careful when performing activities that require alertness, such as driving and operating machinery. Especially at the beginning of treatment, participation in traffic is not recommended.

Fenobarbital contains lactose. If your doctor has told you that you are intolerant to certain sugars, contact your doctor before taking this medicine. Fenobarbital contains sodium. This medicine contains less than 1 mmol of sodium (23 mg) per tablet, which means that it is essentially "sodium-free." Fenobarbital contains wheat starch. This medicine contains only a very small amount of gluten (from wheat starch). It is considered "gluten-free" and is unlikely to cause any symptoms if you have celiac disease. One tablet of Fenobarbital 25 mg contains no more than 2 micrograms of gluten.

#### **How to use fenobarbital teva?**

Follow the advice of your doctor closely when using Fenobarbital Teva. If in doubt, consult your doctor or pharmacist.

**Dosage:** The dosage of fenobarbital should be determined individually based on the effect.

**Adults:** 100-250 mg per day (=24 hours) divided into 2 doses.

**Premature infants:** 2-3 mg per kilogram of body weight per day (=24 hours), for example, for 2.5 kg 6.25 mg or 1/4 tablet of 25 mg per day (=24 hours).

**Newborns:** 3-4 mg per kilogram of body weight per day (=24 hours), for example, for 3.5 kg 12.3 mg or 1/2 tablet of 25 mg per day (=24 hours), divided into 2 doses.

**Children aged:** 2-12 months: 4 mg per kilogram of body weight per day (=24 hours), for example, for 6 kg 24 mg or 1 tablet of 25 mg per day (=24 hours), divided into 2 doses.

**Children weighing:** 10-20 kg: 5 mg per kilogram of body weight per day (=24 hours), for example, for 15 kg 75 mg or 3 tablets of 25 mg per day (=24 hours), divided into 2 doses.

20-30 kg: 4 mg per kilogram of body weight per day (=24 hours), for example, for 25 kg 100 mg or 2 tablets of 50 mg per day (=24 hours), divided into 2 doses.

30-45 kg: 3.5 mg per kilogram of body weight per day (=24 hours), for example, for 35 kg 125 mg or 2 tablets of 50 mg and 1 tablet of 25 mg per day (=24 hours), divided into 2 doses.

If you notice that Fenobarbital is too strong or too weak, consult your doctor or pharmacist.

#### **Method of use**

The tablets are best taken with plenty of water.

What to do if you have used more Fenobarbital than you should If you have taken too much Fenobarbital Teva, contact your doctor immediately.

#### **What to do if you have forgotten to use Fenobarbital**

If you miss a dose, use it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue with your normal dosage schedule. Do not take a double dose to make up for a missed one.

#### **If you stop using Fenobarbital**

The dosage should not be stopped suddenly. See also the section "Be extra careful with Fenobarbital Teva." If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

#### **Possible side effects**

Like all medicines, Fenobarbital can cause side effects, although not everyone gets them.

**The following side effects may occur:** drowsiness, lethargy, difficulty seeing, spontaneous eye movements (nystagmus), dizziness, headache, staggering, nausea, vomiting, skin rash, very rarely with skin death (toxic epidermal necrolysis (TEN)), softening of bone due to vitamin D deficiency, certain connective tissue diseases (lupus erythematosus), acute psychotic reaction.

**Rarely occur:** anemia, blood disorders.

**Very rarely occur:** potentially life-threatening skin rash: Stevens-Johnson syndrome and toxic epidermal necrolysis. In children, the following may occur: irritability, hyperactivity, aggression, sleep disorders.

**In the elderly, the following may occur:** excitement, confusion. There have been reports of bone disorders including thinning of the bone (osteopenia, osteoporosis) and bone fractures. If you are being treated with an anti-epileptic drug for a long time, have previously had osteoporosis or are using steroids, consult your doctor.

When one of the side effects becomes serious or if you experience a side effect that is not listed in this leaflet, consult your doctor or pharmacist.

#### **How to store fenobarbital teva?**

Keep out of the sight and reach of children.

Do not use Fenobarbital after the expiry date stated on the packaging after "do not use after" or exp. The first 2 digits indicate the month, the last digits indicate the year.

Store below 25°C, in the original packaging. Keep the packaging carefully closed to protect against moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist what to do with medicines that are no longer needed. These measures will help protect the environment.