

PACKAGE LEAFLET: INFORMATION FOR THE USER

Teotard

Teotard 200 mg prolonged release capsule, hard

Teotard 350 mg prolonged release capsule, hard

THEOPHYLLINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TEOTARD is and what it is used for
2. Before you take TEOTARD
3. How to take TEOTARD
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1. WHAT TEOTARD IS AND WHAT IT IS USED FOR

Theophylline is a medicine that expands bronchi (bronchodilator). By reducing the tension of their smooth muscle increases the flow of air through the bronchi and thus facilitates breathing. Because it improves the transport of bronchial mucus (mucociliary clearance), facilitates expectoration. It also acts on the smooth muscle of blood vessels, bile duct and digestive organs. It stimulates the respiratory center and heart, increases the strength of contractions of the diaphragm and respiratory muscles, secretion of urine and prevents the release and action of some intermediaries (mediators) of allergic reactions.

Medicine Teotard is prepared according to a special high technology process. The capsules are small pellets from which theophylline is released slowly, which is why there is no abrupt increase or decrease of concentration.

Medicine is designed to treat all forms of asthma in children and adults with chronic obstructive bronchitis, pulmonary emphysema, pulmonary hypertension in chronic pulmonary heart and central conditioned disorders of breathing during sleep.

2. BEFORE YOU TAKE TEOTARD

Do not take TEOTARD

- If you are allergic (hypersensitive) to theophylline or any ingredients of Teotard;
- If you are allergic (hypersensitive) to xanthine preparations (for example, caffeine, theobromine, pentoxifylline);
- If you have not long ago suffered from an acute myocardial infarction;
- If you have an acute cardiac arrhythmias (acute tachyarrhythmias).

Take special care with TEOTARD if you

- If you are being treated for heart failure, high blood pressure, unstable angina or other heart disease, epilepsy, ulcers in the digestive tract, disruption in the work of thyroid gland (hyperthyroidism), hepatic disorders (especially cirrhosis), or kidney;
- If you have hypertrophic obstructive cardiomyopathy, porphyria, reduced concentration of oxygen in the blood (hypoxemia), prolonged fever, pneumonia, viral infection (particularly influenza);
- If you have ever had ulcer in the digestive tract or
- If you are taking other medicines (see Taking other medicines with Teotard).

If you have any of the listed diseases and if you are older than 60 years, the doctor will carefully monitor you during treatment and, if necessary, reduce the dose of Teotard.

Before treatment with Teotard warn your doctor:

- If you start or stop taking other medicines,
- If you start or stop smoking,
- If you change the diet.

In the above-mentioned cases, the dosage of Teotard should be adjusted.

Medicine Teotard is not suitable for the treatment of children younger than 6 years or lighter than 20 kilos.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

During treatment with Teotard it is not recommend to take theophylline-related medicines (caffeine, theobromine, pentoxifylline), because these substances can increase the stimulating effect of theophylline on the central nervous system.

During the simultaneous administration of allopurinol, cimetidine, ciprofloxacin, disulfiram, phenylbutazone, flvoxamine, fluoroquinolones, furosemide, imipenem, alpha-interferon, isoniazid, calcium antagonists, lincomycin, macrolides, mexiletine, paracetamol, oral contraceptives, probenecid, propafenone, propranolol, ranitidine, tacrine, thiabendazole, ticlopidine, viloxazine or flu vaccines (influenza) and theophylline, the effect of theophylline may be increased. In patients who are simultaneously treated with theophylline and one or more recited medicines, the doctor will monitor the serum concentration of theophylline, and optionally reduce the dose.

During simultaneous taking of medicines for the treatment of epilepsy (e.g., phenytoin, carbamazepine, primidone), barbiturates (phenobarbital and pentobarbital particular), isoproterenol, magnesium hydroxide, moricizine, rifampicin, ritonavir or sulfinpyrazone and theophylline, the theophylline effect can be reduced. In patients who are simultaneously treated with theophylline and one or more recited medicines, the doctor will monitor the serum concentration of theophylline and increase the dosage if necessary. The effect of theophylline may be reduced in smokers.

Theophylline can increase the effect of beta-receptor agonists, diuretics and reserpine.

Theophylline can reduce the effect of adenosine, lithium carbonate, and beta-blockers.

It is necessary to avoid simultaneous treatment with theophylline and beta-receptor blockers because they can reverse the effect of theophylline.

Before possible surgery warn your doctor that you are taking theophylline because the anesthetic halothane can cause serious cardiac arrhythmias.

Taking food and drink with Teotard

During treatment with Teotard it is not recommended drinking of alcoholic beverages and simultaneous consumption of large quantities of beverages and food products that contain methylxanthines (coffee, tea, cocoa, chocolate, cola and similar drinks, energy drinks).

Pregnancy and breast-feeding

Theophylline crosses the placenta and is excreted in breast milk.

Before starting treatment, tell your doctor if you are pregnant or breast-feeding.

Pregnant and breastfeeding women can take the medicine only if it is necessary. A treatment during pregnancy and breast feeding is decided by a doctor.

Women, who are breast-feeding, should carefully observe the child. If it becomes hypersensitive, irritable or cannot sleep, talk to your doctor.

Driving and using machines

TEOTARD should not affect your ability to drive and use machines.

3. HOW TO TAKE TEOTARD

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The dose of theophylline is determined on the basis of clinical effect, Serum concentrations of theophylline and possible side effects. A therapeutic concentration of theophylline in serum is determined in the laboratory. During treatment, a doctor will occasionally refer to the seizure of the blood and check the concentration of theophylline in serum.

The usual dose for adults and adolescents weighting more than 40 kg is 350 mg of theophylline twice daily.

The usual dose for children older than 6 years and weighing more than 20 kg, adolescents and very thin adult patients is 200 mg of theophylline twice a day.

Patients with nocturnal asthma or breathing disorders during sleep can take one dose of Teotard per day, which is taken at bedtime. On average 400 to 700 mg of theophylline is sufficient.

Adolescents and smokers can take unequal doses, higher taken in the evening and lower in the morning.

We recommend that the first dose of medicine Teotard is taken in the evening before bedtime. Take your medicine after a meal with a generous amount of liquid. Do not chew the capsule, swallow it whole.

The duration of treatment will be determined by a doctor.

If you think that the effect of the medicine is too strong or too weak, talk to your doctor or pharmacist.

If you take more TEOTARD than you should

If you have taken more medicine than you should, talk to your doctor or pharmacist.

Excessive doses can cause nausea, vomiting, headaches, insomnia, rapid pulsation of the heart and heart rate. Usually it is enough if a doctor reduces the dose or temporarily revokes the use of theophylline.

After taking a large number of capsules at once, you may experience restlessness, tremors or shaking hands (tremor), delirium, heart rhythm disorders (tachyarrhythmias), sharply reducing blood pressure and convulsions.

If you forget to take TEOTARD

Do not take a double dose to make up for the forgotten tablet.

If you miss a dose, take the next dose at the usual time and continue to use the medicine as instructed by a doctor.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TEOTARD can cause side effects, although not everybody gets them.

Very common:	more than 1 treated person of 10
Common:	1 to 10 treated persons of 100
Uncommon:	1 to 10 treated persons of 1000
Rare:	1 to 10 treated persons of 10000
Very rare:	less than 1 treated person of 10000
Not known:	frequency cannot be estimated from the available data

Very common side effects include palpitations, headache, dizziness, insomnia, abdominal pain, nausea, vomiting, diarrhea, anxiety and irritability.

When the serum concentrations of theophylline are higher than therapeutic (in hypersensitive patients may also be sooner), side effects may include: sleep disorders, urinary excretion of greater amounts (increased diuresis), recurring vomiting, hand tremors (shaking), fever, delirium, disorders heart rate (tachycardia), rapidly lowering blood pressure and cramping.

Other: reduced levels of potassium in your blood (hypokalemia), increased levels of calcium in the blood plasma (hypercalcemia), and elevated levels of blood glucose (hyperglycemia), increased concentration of uric acid in the blood (hyperuricemia).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE TEOTARD

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use TEOTARD after the expiry date which is stated on the label.

Shelf life: 5 years.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What TEOTARD contains

- Medicinal active substance is theophylline. One prolonged release capsule, hard contains 200 mg or 350 mg of theophylline.
- The other ingredients are povidone, talc (E553b), copolymer (type A), ammonium methacrylate copolymer (type B) ammonium methacrylate, anhydrous colloidal silicon dioxide, and triethyl citrate (E1505) in the contents of the capsules and gelatin (E441), titanium dioxide (E171), quinoline yellow dye (E104) and indigo carmine (E132) in the coating.

What TEOTARD looks like and contents of the pack

The body of prolonged release capsules, hard (200 mg and 350 mg) is dark green and transparent, and the sealing is dark green and opaque. The contents of the capsules are white pellets.

There are boxes with 40 hard prolonged release capsules in the blister. They contain 4 blisters with 10 capsules each.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Krka d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia