PACKAGE LEAFLET: INFORMATION FOR THE USER

TEOKAP SR

100 mg prolonged release capsules, 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 TEOKAP SR IS AND WHAT IT IS USED FOR

Teokap SR is a medicine used in the treatment of asthma (bronchodilator).

Teokap SR is used in the treatment and prevention of respiratory distress caused by obstruction of the airways (bronchoconstriction) in patients with persistent (lasting) bronchial asthma or moderate to severe obstructive (constrictive) respiratory tract disease (eg. Chronic bronchitis and pulmonary emphysema).

Note: When theophylline is used in long-term treatment of the above mentioned diseases, it is recommended to combine it with other bronchodilator and anti-inflammatory medicines (eg, long-acting β-sympathomimetics and glucocorticoids).

Sustained release preparations of theophylline, such as a medicine Teokap SR, are not suitable for acute treatment of status asthmaticus (severe asthma crisis), acute asthmatic attack or bronchospasm (crisis of respiratory distress due to bronchoconstriction).

2. BEFORE YOU TAKE TEOKAP SR

Do not take Teokap SR:

- If you are hypersensitive (allergic) to theophylline or any of the other ingredients of Teokap SR;
- if you have recently had a heart attack;
- if you suffer from acute cardiac arrhythmias with rapid heartbeat (tachycardia).

Take special care with Teokap SR:

- if you suffer from unstable angina pectoris (coronary heart disease);
- If you have a tendency to arrhythmias with rapid heartbeat (tachycardia);
- if you suffer from very high blood pressure;
- if you suffer from hypertrophic obstructive cardiomyopathy (chronic disease of heart muscle);
- if you suffer from hyperactivity of the thyroid gland (hyperthyroidism);
- if you suffer from epilepsy;
- if you have a gastric and / or duodenal ulcer;
- if you suffer from porphyria (a specific metabolic disorder);
- if you suffer from liver or kidney dysfunction;
- if you are receiving electroconvulsive therapy, given that theophylline may extend spasm (cramp).

If you have any of the conditions listed above or have had them in the past, please consult your doctor before taking the medicine Teokap SR.

Children

The rate of elimination of theophylline in children depends on age. Especially in premature babies and babies under 6 months there is an increased risk of overdose.

Elderly patients

Using medicine Teokap SR in elderly and / or seriously ill patients is associated with an increased risk of overdose and therefore these patients should be kept under constant surveillance by measuring blood levels (see section 3).

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 and herbal medicines.

The simultaneous use of the medicine Teokap SR and below listed medicines enhances the effect of the medicine Teokap SR:
• medicines containing other xanthine;
• ß-sympathomimetics (medicines to stimulate the autonomic nervous system);
• drinks containing caffeine such as coffee, tea, cola, mate, guarana, "energy" drinks;
• Oral contraceptives (birth control pills);
• certain antibiotics (eg. The macrolide antibiotics such as erythromycin or troleandromicin, clarithromycin, josamycin, spiramycin);
• quinolones or fluoroquinolones (antibiotics that belong to the group of inhibitors of the enzyme gyrase, particularly ciprofloxacin, enoxacin, pefloxacin, see below *);
• imipenem (antibiotics, adverse effects that can be expected due to the simultaneous use of cramps);
• hydrazide isonicotinic acid (an antibiotic);
• thiabendazole (medicine against fungi and intestinal parasites);
• calcium channel blockers (such as verapamil, diltiazem.
They are used for the treatment of cardiovascular diseases);
• propranolol, propafenone, mexiletine, ticlopidine (medicines for the treatment of cardiovascular diseases);
• cimetidine, ranitidine (medicines to reduce gastric acid production);
• allopurinol, febuxostat (medicines for the treatment of gout);
• fluvoxamine, viloxazine (antidepressants);

• alpha-interferon and peginterferon alfa (medicines for stimulation of the immune system)
• rofecoxib (anti-rheumatic medicines);
• pentoxifylline (remedy for disorders of circulation);
• disulfiram (used to treat alcohol dependence);
• phenylpropanolamine (a medicine that affects the reduction of appetite);
• zafirlukast and zileuton (medicines for the treatment of asthma);
• vaccines against influenza and tuberculosis;
• idrocilamid (a medicine for the treatment of painful muscle contractions);
• acyclovir (used for the treatment of viral infections);
• etintidin.

In the case of concomitant use with one of these medicines, theophylline levels should be controlled, and the dosage adjusted if necessary. This also applies in the following cases, after you stop using one of these medicines.

* When theophylline is administered concomitantly with ciprofloxacin, theophylline dose must be reduced to no more than 60%, with enoxacin at no more than 30% and to clinafloxacin grepafloxacine or 50% of the recommended dose.
Other quinolones (eg. Pefloxacin or Pipemidic acid) may potentiate the effects of medicines containing theophylline. Therefore, frequent check of concentrations of theophylline is strictly recommended in concurrent treatment with quinolones.

The efficiency of medicine Teokap SR can be reduced, and it is possible that it will be necessary to increase the dose of theophylline with concomitant use of the following medicines:
• barbiturates such as phenobarbital, pentobarbital, and primidone;
• carbamazepine (a medicine for treatment of epilepsy);
• phenytoin, fosphenytoin (antiepileptics);
• Rifampicin and rifapentine (antibiotics);
• sulfinpyrazone (and anti-inflammatory medicine that prevents the formation of blood clots);
• ritonavir (medicine for the treatment of HIV infection);
• aminoglutethimide;
• hypericin part of St. John's Wort (St. John's wort);
• in smokers.

The effect of lithium carbonate, β-blockers, adenosine and benzodiazepine can be altered or reduced if taking the medicine Teokap SR at the same time.
Theophylline can enhance the effects of diuretics such as furosemide (medicines which promote urination).

Taking food and drink with TEOKAP SR
Caffeine enhances the effect of theophylline. Smoking increases the breakdown of theophylline and hence weakens its effect. At the same time alcohol can further influence the reaction (see Chapter 2, "The impact of medicine Teokap SR on the ability to drive and use machines").

Concomitant intake of food has no influence on the activity of the medicine.

Pregnancy and breastfeeding
Pregnancy

Since the experience of using theophylline during the first trimester of pregnancy is still insufficient, the use of theophylline during this period should be avoided.

During the second and third trimester, theophylline should be used only after careful evaluation of the risks and benefits of a doctor, as it goes in the fetal circulation and may exert effects.

If the patient was treated at the end of pregnancy, uterine contraction can be inhibited. Infants who were exposed to theophylline during pregnancy should be carefully monitored for the effects of the medicine.

Breastfeeding

Theophylline passes into breast milk. For this reason, therapeutic doses of theophylline in nursing mothers should be the lowest possible. It is recommended to carry out breastfeeding as much time before taking the medicine. If higher therapeutic doses are necessary, breast feeding must be stopped.

Driving and using machines

Teokap SR may have an impact on the speed of reaction to such an extent that, for example, the ability to drive, using machines, as well as working at height or without protective safety equipment can be reduced.

This is especially true if the medicine Teokap SR is used in combination with alcohol or other medicines that affect the speed of response.

Other warnings

This medicine contains sucrose (sugar). Therefore, please consult with your doctor before taking the medicine Teokap SR, if you know that you suffer from intolerance to certain sugars.

3. HOW TO TAKE TEOKAP SR

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 dosage of the medicine Teokap SR must be adapted to the individual in accordance with the effects of the medicine.

If possible, dose should be determined after the measurement of serum levels of theophylline (concentration of theophylline in the blood, the target range of 8-20 mg / ml). Serum levels of theophylline in particular need to be checked in cases of reduced efficiency or if you experience side effects.

To determine the initial dose all previous treatments theophylline or its compounds should be taken into account because of the possible need for dose reduction.

The dose is determined by taking into account normal weight as the body weight of the patient, considering that theophylline is not absorbed in fatty tissue; in particular need to take this into account in obese patients.

The daily maintenance dose for an adult is about 11-13 mg of theophylline per kilogram (kg) body weight.

Teokap SR

Due to faster elimination of theophylline, children aged over 6 months, as well as smokers, need higher doses of theophylline by weight than adult non-smokers. On the other hand, in infants younger than 6 months and in the elderly (over 60 years) the excretion of theophylline is extended / prolonged.

Dosing in patients who stopped smoking should be carefully determined due to increased levels of theophylline in the blood.

The excretion of theophylline is often prolonged in patients with heart failure (cardiac insufficiency), serious lack of oxygen, hepatic dysfunction, pulmonary inflammation, viral infections (particularly influenza), in elderly patients and during the simultaneous use of certain medications (see Section 2 "Taking other medicines ").

The recommended dosing scheme

Unless otherwise stated, the following are recommended doses, and associated with age:

Age in years	body weight in kg*1	daily dosage of theophylline in mg per kg of body weight
Children		
1-5	5-20	24

6-8	20-25	24
8-12	25-40	20
Adolescents		
12-16	40-60	18
Adults		
Non-smokers	50-70	11-13
Smokers	50-70	18

*1 in cases of obese patients, one needs to take into account normal body weight

If the preparation of theophylline, which has no properties of sustained release of theophylline should be replaced with the one that has the properties of sustained release of theophylline, it must be borne in mind that it may be necessary to reduce the daily dose. If the theophylline formulation with extended release properties should be replaced by another, such as the product of another manufacturer, it is necessary to control serum levels of theophylline (concentration of theophylline in the blood). This is also recommended in cases of administration / application of high doses.

If you experience symptoms of an overdose, depending on the severity of these symptoms, you need to skip the next dose or reduce it by 50% in accordance with the instructions of doctors. In any case, it is always necessary to consult a doctor when it comes to any adjustment / change of doses.

Method of administration

Through the mouth (oral administration).

Take medicine Teokap SR after meals with plenty of fluids. The capsule should not be chewed.

If you have difficulty swallowing capsules, you can open up and swallow the entire contents of the capsules with plenty of fluids.

Treatment is required to start, if possible, in the evening, shortly before going to bed, and the dose may be increased slightly for 2-3 days.

Then, it is necessary to divide the daily dose into two parts: the first is taken in the morning with breakfast, and the other in the evening before going to bed.

The dose should be increased or reduced if the doctor determines so.

Duration of administration

The medicine Teokap SR is taken only on the advice of a doctor.

The duration of administration depends on the nature, severity and course of the disease, and is determined by the doctor.

If you take more Teokap SR than you should

In case of overdose with Teokap SR, with serum levels of theophylline up to 20 mg / ml, there are usually apparent known side effects of theophylline (among other things, gastrointestinal discomfort, excitation of the central nervous system, cardiac arrhythmias), but with increased intensity.

At the levels of theophylline in the blood above 25 mg / ml, there may appear serious cardiac or cerebral functional disorders, for example, seizures or serious cardiac arrhythmia, and cardiovascular failure. Such reactions are not necessarily marked by the emergence of mild side effects. In the case of intoxication by theophylline products with extended release properties, symptoms of intoxication can occur with delay.

Patients with increased individual sensitivity to theophylline may experience severe symptoms of overdose even at lower levels in the blood than those mentioned here.

If overdose is suspected, you should immediately inform the doctor. The doctor should, depending on when the capsules are taken, to implement the following measures:

In the case of mild symptoms of overdose

The medicine Teokap SR should be discontinued and the serum levels of theophylline should be determined. In case of continuing treatment, the dose should be appropriately reduced.

Treatment with all theophylline intoxication

Gastric lavage may be a sensible move to 2 hours after administration of the medicine. For further elimination of toxins, repeated administration of activated charcoal, preferably in combination with effective laxative (eg. Glauber's salt).

In the case of reaction on the central nervous system (eg. Agitation and seizures)

Diazepam i.v., 0.1-0.3 mg / kg body weight to 15 mg

In cases of life-threatening symptoms:

- monitor vital functions;
- maintain the airway opening (intubation);
- give oxygen;
- if necessary, administer plasma expanders intravenously;
- test and, if necessary, adjust water and electrolyte balance;
- hemoperfusion (see below).

In cases of alarming cardiac dysrhythmia

Intravenous administration of propranolol in non-asthmatic individuals (1 mg in adults, 0.02 mg / kg body weight in children), use of this dose can be repeated every 5-10 minutes until the rhythm is normal or to a maximum dose of 0.1 mg / kg.

Caution:

Propranolol can initiate serious bronchospasm in asthmatics. Asthmatic patients should be treated with verapamil.

In particularly serious cases of intoxication, detoxification can be achieved by hemoperfusion / hemodialysis (kidney dialysis).

Further options for the treatment of medicine intoxication with Teokap SR are determined depending on the severity, clinical course, and depending on the symptoms.

If you forget to take Teokap SR
If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you stop taking Teokap SR
Do not stop taking TEOKAP SR unless your doctor advises you to do so.

If you have any further questions about the application of Teokap SR, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Teokap SR may cause side effects.
Possible side effects

Cardiovascular disorders

Very common: rapid, irregular heartbeat, palpitations, low blood pressure

Gastrointestinal disorders

Very common gastrointestinal disorders, nausea, vomiting, diarrhea

Unknown: stimulation of gastric acid production

The weakening of muscle tone of the lower esophageal sphincter may potentiate the already existing nocturnal reflux, or restore the contents of the stomach (gastroesophageal reflux, heartburn).

Immune system disorders

Uncommon: hypersensitivity reactions to theophylline (eg, rash, pruritus, urticaria, bronchospasm), including severe allergic (anaphylactic) reactions.

The impact on metabolism and nutrition

Very common: reduction of blood potassium levels (hypokalemia), increased levels of calcium, increase in blood sugar (hyperglycemia), as well as increased levels of uric acid (hyperuricemia).

Nervous system

Very common: headache, state of excitation (excitement), tremor (shaking), restlessness, insomnia, dizziness.

Unknown: convulsions.

Renal and urinary disorders

Very common: increased urine output (diuresis)

Undesirable effects may be more intense when there is an individual hypersensitivity or overdose (blood levels of theophylline than 20 mg / ml).

In particular, the blood levels of theophylline (concentration of theophylline in the blood) of more than 25 mg / ml may produce symptoms of intoxication such as convulsions, sudden drop in blood pressure, heart rhythm disorders (ventricular arrhythmia), cardiovascular failure, disintegration / dissolution of skeletal muscle (rhabdomyolysis) and serious phenomena in the gastrointestinal tract (eg, gastrointestinal bleeding).

If you notice any side effect, talk to your doctor or pharmacist.

5. HOW TO STORE TEOKAP SR

Keep out of reach and sight of children.
Store the medicine at a temperature below 25° C, protected from light.

Shelf life: 3 years
Teokap SR must not be used after the expiry date stated on the packaging.

Medicines should not be disposed of via waste water 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 does Teokap SR contain?

The active ingredient is theophylline.

1 capsule of Teokap SR hard capsule contains 100 mg of theophylline.

The other ingredients:
sugar spheres (micropellets sugar and corn starch),

shellac,
talc,
azorubine (E122),
water,
gelatin.

Information for diabetics:
1 capsule of the medicine Teokap SR contains 20.68 mg of sugar micro-pellets.

What Teokap SR looks like and contents of the pack
Teokap hard gelatin capsules with sustained-release medicinal component precisely, No.3, pink TR / TR color; containing whitish, spherical micropellets, and 100 mg of theophylline as active substances.

Teokap SR capsules come in packs of 30 capsules. Each blister contains 15 capsules, with 2 blisters in a box.

Regime of dispensing
The medicine is issued on prescription.

Manufacturer
NOBEL İLAÇ SANAYİİ VE TİCARET A. Ş.
Ümraniye 34768 İstanbul Türkiye

Manufacturer of the medicinal product
NOBEL İLAÇ SANAYİİ VE TİCARET A. Ş.
Sancaklar 81100 Düzce Türkiye