

PACKAGE LEAFLET: INFORMATION FOR THE USER

DUROFILIN RETARD

125 mg prolonged-release capsules

250 mg prolonged-release capsules

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 durofilin retard is and what it is used for
2. Before you use durofilin retard
3. How to use durofilin retard
4. Possible side effects
5. How to store durofilin retard
6. Further information

1. WHAT DUROFILIN RETARD IS AND WHAT IT IS USED FOR

Durofilin retard medicine has for an active ingredient the theophylline, a bronchodilator, which is one of the methylxanthines.

How Durofilin retard works

Durofilin, extended-release capsules contain theophylline, a bronchodilator that expands the airways and thus speeds up the breathing.

When to use Durofilin retard medicine?

Your doctor may prescribe this medication to you in order to make you breathe easier if you suffer:

- from asthma
- from chronic obstructive pulmonary disease
- when the previous conventional therapy of these diseases is not successful.
- Durofilin retard capsules can be used to prevent the occurrence of shortness of breath, or for the relief of symptoms when this situation occurs.

2. BEFORE YOU USE DUROFILIN RETARD

Warn your doctor if you are taking other medicines, have a chronic disease, a metabolism disorder, you are hypersensitive to some of the medications, or have had an allergic reaction to some of them.

Do not use Durofilin retard

- if you are allergic to theophyllin or other xanthines or any of the other ingredients of Durofilin retard
- In children, concomitant use of Durofilin retard and ephedrine (a medicine that is found in many cold medicines and decongestants drops for the nose) is contraindicated. Therefore, if Durofilin retard medicine is prescribed to your child, tell your doctor about which medications your child is using.

Do not take the medicine Durofilin retard if you suffer from porphyria (a group of diseases characterized by disorders of enzymes).

Warnings and Precautions

Particular vigilance is required in the application of this medicine in children because of the possibility of serious adverse reactions and enters into a large number of interactions.

Tell your doctor if you:

- are pregnant or breast-feeding
- you smoke or drink alcohol
- you are allergic to theophylline or other ingredients of Durofilin retard
- have a flu
- you have ever had an epileptic attack
- have or have had ulcer (ulcers) in the stomach
- If you have high blood pressure
- not feeling well, you have a fever or chills.
- Are taking other medications that contain theophylline or aminophylline.
- have any of the following: viral infection, liver problems, heart problems, low levels of potassium in the blood, porphyria, problems with the thyroid gland.

Using Durofilin retard with food and drink

- Durofilin retard capsules should be taken after meals.
- Do not chew or suck the Durofilin retard capsules. If you have trouble swallowing the capsule, you can empty the contents of the capsule into the spoon and swallow it with, for example, yoghurt.

Pregnancy and breast-feeding

- It is not recommended to use Durofilin in pregnant women, since it is known that theophylline goes through the placenta, and its safety in pregnancy has not been adequately tested.
- Theophylline passes into the breast milk, therefore Durofilin retard medicine should be administered with caution when used by nursing mothers.

The influence on the psychophysical abilities

Unknown.

Using other medicines

- You should bear in mind that this information may also apply to medicines that you no longer drink, as well as the medication that you plan to take in the future. Tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription.
- Before you start taking Durofilin retard tell your doctor if you use any of the following medications:
- oral contraceptives (medicines to prevent pregnancy)
- medicines for the treatment of epilepsy (barbiturates, carbamazepine, phenytoin)
- antibiotics (ciprofloxacin, erythromycin, clarithromycin, norfloxacin, ofloxacin)
- medicines for the treatment of peptic ulcer disease (gastric ulcer or duodenal ulcer) - (cimetidine, nizatidine)
- medicines for heart disease (diltiazem, isoprenaline, verapamil, beta-blockers, adenosine, moracizin, mexiletine, propafenone),
- medicines for the treatment of cancer (methotrexate, aminoglutethimide, lomustine)
- medicines for the treatment of depressive states (lithium, fluvoxamine, preparations containing St. John's wort)
- medicine for the treatment of tuberculosis (isoniazid, rifampicin)
- medicine for the treatment of gout (allopurinol, sulfapyrazone)
- medicine for the treatment of diseases of the thyroid gland (carbimazole)
- medicine for the treatment of alcoholism (disulfiram)
- antifungal medication (fluconazole, ketoconazole)
- anti-parasite medication (thiabendazole)
- cure for the treatment of vascular disease (oxpentifylline)
- cure for the treatment of herpes, cancer, leukemia, and hepatitis (interferon)
- cure for the treatment of anxiety, "nervousness" (benzodiazepines)
- antiviral medicine (ritonavir)
- anesthetic (ketamine and halothane)
- respiratory stimulant (doxapram)
- diuretics (medications for urination)
- steroids
- The flu vaccine
- the other medicines used in the treatment of asthma or breathing problems, such as aminophylline, salbutamol, terbutaline, salmeterol. If in doubt, contact your doctor.

What you need to know about excipients contained in Durofilin retard?

In case of intolerance to some sugars, contact your doctor before using this medicine.

3. HOW TO USE DUROFILIN retard

If you think that Durofilin retard have too weak or too strong effect on your body, you should contact your doctor.

Your doctor will advise you how long to take Durofilin retard.

Durofilin retard medicine is administered orally.

Customary dosages of Durofilin retard capsule with sustained-release formulations are:

Adults:

250-500 mg twice a day (at intervals of 12 hours)

Children:

6-12 years of age (20-30 kg): 125-250 mg twice a day (at intervals of 12 hours)

Elderly:

If you are elderly person, your doctor will perhaps decide that the application of doses that are lower than the above mentioned doses for adults suits you better. In any case, your physician will adjust the dose of Durofilin until an optimal solution of therapy is reached, which may require the measurement of level of theophylline in serum.

It is common that a daily dose not exceed 24 mg / kg body weight for children, and 13 mg / kg for adults.

By measuring the level of theophylline levels 4-8 hours after administration of the medicine and at least 3 days after each dose adjustment, you ensure more accurate determination of the dose necessary for each patient, since there are individual differences in the level of elimination of the medicine.

The table can be used for management of dosing.

LEVEL OF THE MEDICINE IN PLASMA (mcg/ml)	RESULT	Instruction (If clinically indicated)
Below 10	Too low	Increase the dose for 25 %
10-20	Correct	Maintain the dose
20-25	Too high	Reduce the dose by 10%
25-30	Too high	Pass the next dose and reduce the following doses by 25%
Over 30	Too high	Pass the next two doses and reduce the following doses by 50%

It is recommended to re-check the level of medicine in plasma following dose adjustment, and every 6-12 months.

You cannot prove with certainty bioequivalence between different preparations of theophylline sustained release. Once you determine the appropriate dose of Durofilin, your doctor should not prescribe you a treatment with other xanthine derivative without re-determination of the individual doses of the medicine and clinical assessment.

If you use more Durofilin retard than you should

- If you take more Durofilin retard than you should, immediately tell your doctor or pharmacist!

If you forget to use Durofilin retard

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

4. POSSIBLE SIDE EFFECTS

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

The most common side effects are stomach upset, nausea, vomiting, stomach discomfort, palpitations (heart pounding), low blood pressure, headaches, intermittent diarrhea and insomnia.

The stimulation of the central nervous system and urinary urgency may also occur, especially in children.

If you notice any side effects, please inform your doctor or pharmacist about it.

If these symptoms persist for several days, please contact your doctor.

From time to time, your doctor may want to check the levels of potassium in your blood, as well as the values of the theophylline in the blood to make sure you get the correct dose.

5. HOW TO STORE DUROFILIN RETARD

Do Keep out of the reach and sight of children.

Keep out of the reach and sight of children.

Expiry date

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

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 Durofilin retard contains

The active substances:

One capsule with sustained release contains 125 mg of theophylline.

One capsule with sustained release contains 250 mg of theophylline.

The other ingredients:

- Durofilin extended-release capsules, hard, 40x125 mg: sugar spheres; ethyl cellulose; povidone; talk.
- Capsule ingredients: gelatin, patent blue E131 C.I. 42051, E151 Brilliant black C.I. 28440, titanium dioxide E171 C.I. 77,891th
- Durofilin, capsule with sustained release, solid, 40x250 mg: sugar spheres; ethyl cellulose; povidone; talk.
- Capsule ingredients: gelatin, Sunset yellow E110 C.I. 15985, Quinoline yellow E104 C.I. 47005, titanium dioxide E171 C.I. 77 891st

PACKING

Durofilin retard 125 mg: - capsule with extended release, solid- - 4 blisters with 10 capsules

Durofilin retard 250 mg: - capsule with extended release, solid- - 4 blisters with 10 capsules

Pharmacotherapeutic group: Medicines for systemic use in obstructive pulmonary disease

Anatomical-therapeutic-chemical classification: R03DA04

The regime of dispensing

The medicine is issued on prescription.

Manufacturer

Health A.D.

Vlajkova 199, Leskovac, Serbia

The manufacturer of a medicinal product

Health A.D.

Vlajkova 199, Leskovac, Serbia