PACKAGE LEAFLET: Information for the patient

EUFILINE

Solution for injection – (202 mg + 50.5 mg) / 10 ml (2.5%)

Solution for injection – (192 mg + 48 mg) / 2 ml (12%)

(Theophylline, Ethylenediamine)

EUFILINE

Sugar-coated tablets – 100 mg

(Aminophylline)

Read this leaflet carefully before you start taking this medicine.

- 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 illnes are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. WHAT EUFILINE IS AND WHAT IT IS USED FOR

Aminophylline is a complex of theophylline and ethylenediamine; the latter improves solubility and absorption of theophylline.

Aminophylline directly releases the musculature in bronchi and blood vessels of the lungs, stimulates the central nervous system, promotes diuresis, stimulates gastric acid secretion, reduces pressure of the lower esophageal sphincter and inhibits uterine contractions. Theophylline is also a central respiratory stimulant.

Eufiline is used for the treatment and prophylaxis of reversible bronchospasms associated with asthma or chronic obstructive pulmonary disease.

2. BEFORE YOU TAKE EUFILINE

Do not take Eufiline:

- if you are hypersensitive to xanthines (theophylline, caffeine, theobromine) or ethylenediamine or to any of the excipients of this medicine;
- if you suffer from epilepsy (the convulsive threshold may be lower);
- if you have tachyarrhythmia;
- in acute myocardial infarction;
- if you suffer from acute porphyria.

Intravenous aminophylline is best avoided in patients already taking theophylline, aminophylline, or other xanthine-containing medications.

The use of Eufiline is not recommended in children under 1 year old.

Take special care with Eufiline

Ask your doctor before taking Eufiline.

Aminophylline should be used with caution:

- in patients with peptic ulceration, hyperthyroidism, diabetes, glaucoma, hypertension or other cardiovascular disease;
- in patients suffering from heart diseases (angina pectoris, arrhythmia, heart failure), hepatic or renal dysfunction, acute febrile illness;
- in the elderly, smokers and patients who consume alcohol;
- during pregnancy and breastfeeding.

Intravenous injections of aminophylline must be given very slowly to prevent dangerous CNS and cardiovascular adverse effects resulting from the direct stimulant effect.
Avoid excessive dosage in obese patients; dose should be calculated on the basis of ideal weight for height.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Eufiline.
Please contact your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor for the treatment with Eufiline if you get any other medicine during treatment.

It is particularly important to inform your doctor that you are taking:

- substances that can reduce levels of theophylline such as aminoglutethimide, barbiturates, hidantoins, charcoal, carbamazepine, isoniazid, loop diuretics, ketoconazole, rifampicin, cigarette smoke, sulfinpyrazone, sympathomimetics (beta - agonists and thioamines), ritonavir, St. John's-wort *(Hypericum perforatum)*;
- substances that can increase levels of theophylline such as allopurinol, beta - blockers (non-selective), calcium channel blockers, cimetidine, oral contraceptives, corticosteroids, disulfiram, ephedrine, influenza vaccine, interferon, macrolides, mexiletin, quinolones, thiabendazole, thyroid hormones, isoniazid, fluvoxamine, deferasirox.

Carbamazepine and loop diuretics can reduce and also increase theophylline levels.

Theophylline can affect the following medicines: benzodiazepines, halothane, ketamine, lithium, non-depolarizing muscle relaxants and propofol.

This interaction list is not complete. There are other drugs that may interact with Eufiline.

Taking Eufiline with food and drinks

Eufiline 100 mg sugar coated tablets should be taken after food.

Pregnancy

Ask your pharmacist or doctor for advice before taking this medicine!

Theophylline crosses placenta, and neonatal irritability and apnoea have been reported. Therefore, Eufiline should not be taken unless the potential benefit outweighs the potential risk to the fetus. (Category C).

Breastfeeding

Theophylline is distributed into milk and may occasionally induce irritability or other signs of toxicity in nursing infants, thus Eufiline should not be taken unless the potential benefit outweighs the potential risk to the infant. In such cases, breast-feeding should be done immediately before taking the medicine.

Driving and using machines

There is no evidence that Eufiline affects the ability to drive and use machines.

Important information about some of the excipients of Eufiline

Eufiline sugar-coated tablets contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Eufiline sugar-coated tablets also contain sodium benzoate.

3. HOW TO TAKE EUFILINE

Always take this medicine exactly as your doctor has told you. If you are not sure, contact your doctor or pharmacist. If you feel that the effects of this drug are too strong or too weak, talk to your doctor or pharmacist.

Eufiline is a drug with a low therapeutic index (the therapeutic dose is near the toxic dose), hence its dosing should be done with extreme caution.

Eufiline – (202 mg + 50.5 mg) / 10 ml (2.5%) – solution for injection:
Eufiline – (192 mg + 48 mg) / 2 ml (12%) – solution for injection:

Eufiline may be given intravenously by slow injection or infusion under cautious monitoring.
Eufiline must be given by very slow intravenous injection (over at least 20 minutes).
In intravenous administration, blood theophylline levels should be monitored.
Avoid excessive dosage in obese patients, dose should be calculated on the basis of ideal weight for height.
In adults and children, who have not been taking theophylline, aminophylline, or other xanthine containing medication, a loading dose of 0.6 – 3.1 mg / kg body-weight, may be given intravenously over 20 to 30 minutes by slow injection or infusion.
Depending on the status of the patient, the maintenance dose, given intravenously, may be considered as follows:
Non-smoking patients, given intravenously: 0.5 to 0.7 mg / kg body weight / hour.
Elderly patients and those with cor pulmonale, given intravenously: 0.3 to 0.6 mg / kg body weight / hour.
Patients with congestive cardiac failure, given intravenously: 0.1 – 0.5 mg / kg body weight / hour.
Children aged 9 years to 16 years and young adult smokers, given intravenously: 0.8 – 1 mg / kg body weight / hour.
Children aged 1 to 9 years, given intravenously: 1 – 1.2 mg / kg body weight / hour.

Eufiline – 100 mg – sugar-coated tablets:
Non-smoking adults: 3 mg / kg every 8 hours.
Elderly patients and those with cor pulmonale: 2 mg / kg every 8 hours.
Patients with congestive cardiac failure: 1 to 2 mg / kg body weight, every 12 hours.
Children aged 1 to 9 years: 4 mg / kg every 6 hours.
Children aged 9 years to 16 years and young adult smokers: 3 mg / kg every 6 hours.

If you take more Eufiline than you should

If you take more Eufiline than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital, or call the emergency to get an opinion on the risk and advice on the actions that should be taken.

During Eufiline overdose, toxicity can occur. Symptoms of overdose include: hypotension, hypokalemia, metabolic acidosis.

If you forget to take Eufiline

If you forget to take one dose (or more than one dose), take the next dose in its usual time.

Do not take a double dose (or higher) to make up the forgotten dose(s).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Most of the side effects are dose-related and disappear when the dose is reduced or the treatment is stopped. Some side effects may occur at the beginning of treatment and disappear spontaneously when the treatment continues.

Side effects that Eufiline can cause are as follows:

- gastroduodenal disorders (nausea, vomiting, anorexia, diarrhoea, gastroesophageal reflux, epigastric pain);
- cardiovascular disorders (palpitations, tachycardia, hypotension, arrhythmia);
- central nervous system / psychiatric disorders (irritability, headaches, insomnia, contractions, confusion, anxiety, dizziness);
- respiratory disorders (tachypnea, inability to breathe);
- eye disorders;
- metabolism and nutrition disorders (low levels of potassium, phosphate or salt in the blood, hyperglycemia, hyperuricemia, lipidic alterations);
- skin and subcutaneous tissue disorders (rash, rash maculo-papular, erythema, pruritus, urticaria, dermatitis exfoliative, Stevens-Johnson syndrome);
- proteinuria, diuresis, fever, facial rash, abnormal secretion of antidiuretic hormone have also been observed.

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

5. HOW TO STORE EUFILINE

Keep out of the sight and reach of children!

Do not use Eufiline after the expiry date which is stated on the package.

Store below 25°C.

6. OTHER INFORMATION

What Eufiline 2.5% solution for injection contains

The active substances are theophylline and ethylenediamine.

Each ampoule of 10 ml contains 202 mg of theophylline and 50.5 mg of ethylenediamine.

Excipients: sodium chloride and water for injection.

What Eufiline 12% solution for injection contains

The active substances are theophylline and ethylenediamine.

Each ampoule of 2 ml contains 192 mg of theophylline and 48 mg of ethylenediamine.

Excipient: water for injection.

What Eufiline 100 mg sugar-coated tablets contain

The active substance is aminophylline.

Each sugar-coated tablet contains 100 mg aminophylline.

Excipients: dipotassium hydrogen phosphate, maize starch, talc, sodium starch glycolate, magnesium stearate, sucrose, gelatin, povidone, titanium dioxide, calcium carbonate, yellow iron oxide, red iron oxide, black iron oxide, indigo carmine, sodium benzoate, shellac, carnauba wax and beeswax white.

Contents of the pack:

Eufiline 2.5% solution for injection:

Box with 10 ampoules.

Eufiline 12% solution for injection:

Box with 10 ampoules.

Eufiline 100 mg sugar-coated tablets:

Box with 60 sugar-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in August 2023.