

UNICONTIN 400/ 600 (CONTROLLED RELEASE TABLETS OF THEOPHYLLINE)

PACKAGE LEAFLET: INFORMATION FOR THE USER

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, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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 health care provider or pharmacist.

What is in this leaflet?

1. What Unicontin 400/600 is and what it is used for?
2. What you need to know before you take Unicontin 400/600?
3. How to take Unicontin 400/600?
4. Possible side effects?
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1. What Unicontin 400/600 tablets is and what it is used for?

These tablets are used to treat asthma and long-term breathing difficulties such as chronic obstructive pulmonary disease. They contain the active ingredient theophylline which belongs to a group of medicines called bronchodilators.

Bronchodilators help stop you wheezing and being breathless. Theophylline also reduces inflammation in airways and relieves the feeling of 'tightness' in their chest. These tablets may be taken by adults and children aged 12 years and above.

2. What you need to know before you take Unicontin 400/600 tablets?

Do not take Unicontin 400/600 tablets if you:

- are allergic to theophylline, or any of the other ingredients of the tablets.
- have porphyria (a rare disease of the blood pigments)

Do not give to your child if they are under 6 months of age or if they are also taking a cough medicine or if they are less than 12 years of age and taking a decongestant containing ephedrine.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking these tablets if you:

- have an irregular heartbeat, high blood pressure or any other heart problems.
- experience worsening of chest symptoms e.g. breathlessness or cough;
- have an over or under-active thyroid gland (hyper/hypothyroidism).
- have a stomach ulcer;
- have liver problems;
- have cystic fibrosis;
- suffer from seizures, fits or convulsions;

- are unwell with a high temperature or fever;
- have a viral infection;
- are addicted to alcohol;
- are male and have difficulty in passing urine (for example due to an enlarged prostate gland);
- smoke, as smoking may alter the way your tablets work.

Taking Other medicines with Unicontin 400/600 tablets.

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including:

- certain other medicines to treat asthma or breathing conditions that contain theophylline, aminophylline, salbutamol, terbutaline or salmeterol, as you may need additional monitoring;
- steroids;
- diuretics to increase urine production;
- oral contraceptives;
- a herbal remedy called St John's Wort (also known as Hypericum perforatum);
- aminoglutethimide, methotrexate or lomustine to treat cancer;
- carbamazepine or phenytoin to treat seizures, fits or convulsions;
- medicines known as barbiturates to help you sleep;
- adenosine, diltiazem, isoprenaline, mexiletine, propafenone, propranolol, verapamil or beta blockers to treat high blood pressure and other heart problems;
- regadenoson or dipyridamol used in heart problems;
- pentoxifylline to treat diseased blood vessels;
- medicines known as benzodiazepines, which are used as a sedative or to treat anxiety;
- aciclovir to treat Herpes viruses;
- sulphinpyrazone or allopurinol to treat gout;
- carbimazole to treat problems with your thyroid gland;
- cimetidine or nizatidine to treat stomach ulcers, indigestion or heartburn;
- certain antibiotics such as ciprofloxacin, clarithromycin, erythromycin, enoxacin;
- fluconazole to treat fungal infections;
- rifampicin or isoniazid to treat tuberculosis;
- ritonavir to treat HIV;
- medicines known as interferons, which you may be taking to treat conditions such as herpes, cancer, leukaemia or hepatitis;
- thiabendazole to treat worms such as threadworms;
- fluvoxamine or lithium to treat depression;
- doxapram to stimulate breathing;
- disulfiram to treat alcoholism;
- a cough medicine or decongestant containing ephedrine.

Talk to your doctor or pharmacist before taking Unicontin 400/600 if:

- you are going to have an operation, as these tablets may interact with certain anaesthetics such as halothane and ketamine.
- you have recently had or are going to have a flu injection.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No known effects

3. How to take Unicontin 400/600 Tablets?

Always take these tablets exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure. Swallow your tablets whole with a glass of water.

Do not crush or chew them.

Unicontin 400/600 tablets may be taken once a day in the evening. It is recommended that Unicontin be taken with meals. Patients should be advised that if they choose to take Unicontin with food it should be taken consistently with food and if they take it in a fasted condition, it should routinely be taken fasted. It is important that the product whenever dosed be dosed consistently with or without food.

Unicontin tablets must be swallowed and not chewed. Infrequently, patients receiving Unicontin tablets may pass an intact matrix tablet in the stool or via colostomy. These matrix tablets usually contain little or no residual theophylline. Safety and effectiveness in children under 12 years of age have not been established with Unicontin tablets.

Dosing initiation and Titration (as anhydrous theophylline)

A. Patients without risk factors for impaired clearance.

Doses as decided & Prescribed by Treating Doctor should be adhered.

B. Patients with risk factors for impaired clearance, the elderly (>60 years), and those in whom it is not feasible to monitor serum theophylline concentrations.

Doses as decided & Prescribed by Treating Doctor should be adhered.

Dosage adjustment based upon serum theophylline concentration*- to be decided by treating physician.

*Dose reduction and/or serum theophylline concentration measurement is indicated whenever adverse effects are present, physiologic abnormalities that can reduce theophylline clearance occur or a drug that interacts with theophylline is added or discontinued.

Maintenance Therapy:

Doses as decided & Prescribed by Treating Doctor should be adhered.

Careful clinical titration is important to assure patient acceptance and safety of the medication. Patients, when stabilised as established by serum theophylline concentration or respiratory function, usually remain controlled without further dosage adjustment. It should be borne in mind however that for reasons stated in the warnings & precautions section, dosage adjustments may be necessary. Serum theophylline levels should be measured periodically (at 6-to-12-month intervals) even in clinically controlled patients.

The elderly as well as patients with congestive heart failure, cor pulmonale and/or liver disease may have unusually low dosage requirements and thus may experience toxicity even at the recommended dosage.

Do not maintain any dose that is not tolerated.

If you take more Unicontin 400/ 600 tablets than recommended

Call your doctor or hospital straight away. People who have taken an overdose may have stomach pains and feel or be sick (possibly vomiting blood). They may also have a fast or irregular heartbeat, low blood pressure, feel very restless, experience overactive reflexes or unusual muscle stiffness, have a fit or even go into a coma.

These symptoms may appear up to 12 hours after the overdose. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show the doctor.

If you forget to take Unicontin 400/ 600 tablets

If you or your child forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Unicontin 400/ 600 tablets

You will probably take these tablets for a long time. Do not stop taking them unless your doctor tells you to, even if you feel better.

If you have any further questions on the use of these tablets, ask your doctor, pharmacist, or nurse.

4. Possible side effects?

Like all medicines, these tablets can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions have been reported in rare cases. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

The following side effects have been reported in patients treated with these tablets:

- Feeling sick.
- Headache.
- Vomiting (being sick), abdominal pain, diarrhoea, heartburn or gastrointestinal disorders (e.g., upset stomach).
- Difficulty in sleeping, agitation, anxiety, or tremors.
- A fast, slow, or irregular heartbeat.
- Dizziness.
- Difficulty in passing urine (especially in men) or passing increased amounts of urine.
- Increased uric acid levels in the blood, which could cause painful, swollen joints.
- Seizures, fits or convulsions.
- Rash or itchy skin.

5. How to store Unicontin 400/ 600 Tablets?

Keep this medicine out of the sight and reach of children.

Store at or below 30° C in dry place, protected from light.

Do not use this medicine after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

6. Other information

What Unicontin 400/ 600 Tablets contains?

- Unicontin 400: Each uncoated tablet contains: Theophylline BP: 400 mg (In a continuous controlled release system).
- Unicontin 600: Each uncoated tablet contains: Theophylline BP: 600 mg (In a continuous controlled release system).
- The other ingredients are Povidone K – 30, Hydroxyethylcellulose, Cetostearyl Alcohol, Purified Talc, Magnesium Stearate, Purified water.

What Unicontin 400/600 tablets looks like and contents of the pack?

Unicontin 400: White, round, flat, bevelled edges, scored uncoated tablets engraved with ‘MM’ logo on one of the facets and ‘U/400’ on the other.

Unicontin 600: White, biconvex, scored uncoated caplets engraved with ‘MM’ logo on one of the facets and ‘U/600’ on the other.

Unicontin 400/ 600: Box of 100 Tablets (10x10’s Blister strip)

Manufactured by:

Modi-Mundipharma Pvt. Ltd.

Modipuram – 250 110

U.P., India

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