

PACKAGE LEAFLET: INFORMATION FOR THE USER

ONTRIL

2mg/5ml Syrup

SALBUMATOL

• 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 ONTRIL is and what it is used for
2. Before you take ONTRIL
3. How to take ONTRIL
4. Possible side effects
5. How to store ONTRIL
6. Further information

1. WHAT ONTRIL IS AND WHAT IS IT USED FOR

ONTRIL contains Salbutamol which belongs to a group of medicines called bronchodilators. These medicines make the breathing easier by widening the airways in the lungs. ONTRIL syrup is intended for use in adults, adolescents and children aged 2 to 12 years.

ONTRIL syrup:

- It helps to open the airways in the lungs and makes the breathing easier;
- It helps easing the symptoms such as chest tightness, audible breathing accompanied by a sound like whistling and coughing associated with asthma.

ONTRIL syrup is used to treat breathing problems in people with asthma (chronic inflammatory disease of the airways), chronic bronchitis (inflammation of the airways) and emphysema (a progressive deterioration of lung tissue). Its action also includes relief and prevention of symptoms caused by exertion or other triggers factors, such as house dust, pollen, cats, dogs and cigarette smoke.

In these cases, the primary treatment is achieved by using the inhalable form of salbutamol. The oral formulations of salbutamol (tablet or syrup), are reserved for patients who cannot receive inhalation therapy.

If your asthma is very active (eg. If you have frequent symptoms, frequent attacks or limited physical ability), you should consult with your doctor, who will, in order to control your asthma, change the therapy or increase the dose of the medicine (eg, inhaled corticosteroids).

If you feel that the medicine is no longer as effective as before, tell your doctor as soon as possible. Your breathing problems may worsen and you may need a different medicine. Do not use an additional dose of ONTRIL syrup, unless you are advised by your doctor.

2. BEFORE YOU TAKE ONTRIL

Do not take ONTRIL

- If you are allergic to Salbutamol or to other ingredients of this medicine
- If you are less than 22 weeks pregnant
- If you suffer from ischemic heart disease or know that you are at risk for developing this disease

Take special care with ONTRIL

Tell your doctor or pharmacist:

- If you think your asthma therapy is less effective than before (relief of your symptoms is weaker or it lasts shorter), contact your doctor as soon as possible. There is a possibility that your asthma worsened and that you will need additional treatment.

Tell your doctor if you:

- suffer from a disease of the thyroid gland;
- have diabetes (diabetes mellitus);
- suffer from heart and blood vessels disease, particularly of certain heart rhythm disorders, angina pectoris (strong pain in the chest, which may spread to the left arm), hypertension (high blood pressure);
- are using other beta-agonists, or bronchodilators such as theophylline;
- have had heart disease or angina pectoris;
- are taking diuretics, which are sometimes used to treat hypertension or heart disorders.

Your doctor may require blood tests in order to control possible changes in your blood, such as hypokalemia (decreased potassium levels in your blood).

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If your asthma is not fully controlled by using ONTRIL syrup, it is possible that the doctor will prescribe other medicines that should be taken at the same time (eg, inhaled or systemic corticosteroids, which are medicines derived from cortisone). Do not reduce the dose or stop the treatment with corticosteroids, without consulting with your doctor, even if you notice improvement of your asthma.

In certain cases, ONTRIL syrup can be combined with anticholinergics, mast cell stabilizer, or theophylline.

You should not simultaneously use ONTRIL syrup and non-selective beta-blockers such as propranolol (including medicines that are used in the treatment of certain heart problems). Warn your doctor if you simultaneously use ONTRIL syrup and cardioselective beta-blocker such as atenolol or metoprolol, as caution is needed.

If you are simultaneously using ONTRIL syrup and theophylline (another anti-asthmatic medicine) or cardioselective beta-blockers, you may experience heart problems.

Taking ONTRIL syrup with food or drink

You can take ONTRIL with or without food.

Pregnancy and breastfeeding

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.

Safety for use in pregnancy has not been demonstrated, therefore the drug should not be used in pregnant women, or those likely to become pregnant, unless the expected benefit outweighs any potential risk.

It is not recommended for nursing mothers unless the expected benefits outweigh any potential risk.

Driving and using machines

No information.

Other warnings

This medicine contains sodium, less than 1 mmol (23 mg) per dose.

3. HOW TO TAKE ONTRIL

Always take ONTRIL exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

Method of administration

ONTRIL syrup is administered orally (by mouth).

Dosage

This medicine should always be taken exactly as recommended by your doctor or pharmacist.

The dosage of the medicine is individual, and it will be determined by your doctor based on the severity of your asthma.

Tell your doctor if you notice the need to take your medicine more often or in higher doses, because in this case a reevaluation of your treatment may be required.

Adults

The usual dose in most cases is 10 ml of syrup (4 mg), 3 or 4 times a day. Do not use more than 80 ml (32 mg) per day.

Children

Give your child the following dose:

- Children between 2-6 years: 2.5 to 5 ml of the syrup (1 to 2 mg of salbutamol), 3 or 4 times a day;
- Children 6-12 years: 5 ml of syrup (2 mg of salbutamol), 3 or 4 times a day;
- Children older than 12 years: 5 to 10 ml of syrup (2 to 4 mg of salbutamol), 3 or 4 times a day.

The highest doses of salbutamol which must not be exceeded are: 32 mg per day in adults, 16 mg per day in children over 12 years, 8 mg per day in children aged 6-12 years and 8 mg per day in children aged 2 to 6 years.

Important Information

ONTRIL syrup does not contain sugar.

ONTRIL syrup is taken undiluted.

If necessary, after taking the appropriate dose of syrup, one can take couple of sips of water to swallow remaining syrup in the mouth.

If you take more ONTRIL than you should

If you take too much ONTRIL, talk to your doctor as soon as possible. Take the medicine bottle to show the doctor. It is possible that you will feel tremors, restlessness (agitation), and drop in blood pressure and heart rhythm problems. You can also experience nausea, vomiting and increased levels of sugar in your blood.

If you forget to take ONTRIL

If you forget to take a dose, take it as soon as you remember. Do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

If you stop taking ONTRIL

Keep taking ONTRIL until the treatment is finished, even if you feel better. Do not suddenly stop your treatment.

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

4. POSSIBLE SIDE EFFECTS

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

- Some people may experience chest pain (due to heart problems such as angina), although the incidence of this is not entirely known. If this happens to you, tell your doctor as soon as possible, but do not stop using the drug if you have not been told by your doctor.

Very common side effects

They can occur in more than 1 in 10 people who use ONTRIL syrup:

- Shaking (tremor), mainly hands.

Common side effects

They can occur in up to 1 in 10 people who use ONTRIL syrup:

- Headaches;
- Muscle cramps;
- Tachycardia (rapid heartbeat), palpitations.

Uncommon side effects

They can occur in up to 1 in 1,000 people who use ONTRIL syrup:

- Heart rhythm disorders: if you experience irregular heartbeats, tell your doctor;
- The peripheral vasodilatation which leads to a drop in blood pressure;
- Hypokalemia (low potassium levels in the blood) (severe forms can manifest as muscle cramps, muscle weakness or fatigue).

Very rare side effects

They can occur in up to 1 in 10,000 people who use ONTRIL syrup:

- Hypersensitivity reactions: angioedema (allergic reaction accompanied by swelling of the face and throat with difficulty in breathing), urticaria (hives), bronchospasm, hypotension (low blood pressure) and collapse (strong and sudden weakness associated with a drop in blood pressure).
- Hyperactivity: a sense of unusual activity, such as anxiety and nervousness.
- Muscle tension.

Reporting of side effects

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 ONTRIL

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

Do not use this medicine after the expiry date which is stated on the carton (3 years). The expiry date refers to the last day of that month.

Do not store above 25 °C.

Use within 30 days after first opening.

Shelf life: 24 months.

6. FURTHER INFORMATION

What ONTRIL contains

ONTRIL 5 ml syrup contains: 2.00 mg of salbutamol (as sulphate).

ONTRIL syrup contains the following excipients: hypromellose, citric acid, banana flavor, sodium benzoate, sodium citrate, sodium chloride, sodium saccharin, purified water

What ONTRIL looks like and contents of the pack

ONTRIL syrup is homogeneous, colorless to slightly yellow solution, banana scented. ONTRIL syrup is supplied in bottles containing 200 ml of syrup with a safety lock for children (CRC / TE).

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosna i Hercegovina