

PACKAGE LEAFLET: INFORMATION FOR THE USER

ONTRIL

2mg tablets

SALBUMATOL SULFATE

• 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

1. WHAT ONTRIL IS AND WHAT IS IT USED FOR

ONTRIL tablets belong to a group of medicines called selective beta-2-adrenergic agonists, which can be used to relax the muscles of the airways and womb. ONTRIL tablets may be used in:

- asthma, to relieve the narrowing of the airways
- chronic bronchitis
- emphysema

2. BEFORE YOU TAKE ONTRIL

Do not take ONTRIL tablets and tell your doctor if you:

- are **allergic** (hypersensitive) to salbutamol or any other ingredients in ONTRIL tablets
- have **threatened abortion (potential miscarriage)** during the **first six months** of pregnancy
- are taking **beta-blockers** such as propranolol

Check with your doctor or pharmacist before taking ONTRIL tablets if you have:

- an **overactive thyroid** gland (thyrotoxicosis).
- **diabetes.**

- a history of heart **disease, irregular heart rhythm or angina.**

Although it is not known exactly how often this happens, some people occasionally experience chest pain (due to heart problems such as angina). Tell your doctor/midwife if you develop these symptoms whilst receiving treatment with salbutamol, but do not stop using this medicine unless told to do so.

Taking other medicines

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

- diuretics, guanethidine, reserpine or methyldopa (to treat high blood pressure)
- monoamine oxidase inhibitors e.g. tranylcypromine (for depression)
- tricyclic antidepressants e.g. amitriptyline (for depression)
- beta-blockers such as propranolol
- corticosteroids
- theophylline (for breathing problems).
- inhaled anaesthetics (advise your doctor or dentist if you are undergoing any dentistry or surgery)
- digoxin (for heart problems)
- xanthines such as theophylline, aminophylline (for asthma) medicines for diabetes

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding tell your doctor or pharmacist before taking this medicine.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a sugar called lactose.

Tests

If you have severe asthma, your doctor may monitor you more closely by carrying out certain tests.

3. HOW TO TAKE ONTRIL

Always take ONTRIL tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Swallow the tablets **with water**

If you notice the tablets are not working as well as before, contact your doctor for advice.

• Adults:

Usual dose is 4mg three or four times a day. Your doctor may increase this gradually up to a maximum of 8mg three or four times a day. Some patients may be treated successfully with 2mg three or four times a day.

• Elderly or patients known to be sensitive to this product or other similar drugs:

Initially 2mg three or four times a day should be given.

• Children 2-6 years:

1-2mg three or four times a day.

• Children 6-12 years:

2mg three or four times a day.

• Children over 12 years:

2-4mg three or four times a day.

- **Children under 2 years:**

Not recommended.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include low levels of potassium in the blood which may cause muscle twitching or weakness and an irregular heart beat.

If you forget to take the tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor immediately if you have:

- unusual movement (a common side effect that may affect up to 1 in 10 people) mainly of the face or tongue;
- blood clots in the veins (an uncommon side effect that may affect up to 1 in 100 people) especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately;
- a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness (the frequency of this side effect cannot be estimated from the available data).

Very common side effects (may affect more than 1 in 10 people) include weight gain; sleepiness; and increases in levels of prolactin in the blood. In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.

Common side effects (may affect up to 1 in 10 people) include changes in the levels of some blood cells, circulating fats and early in treatment, temporary increases in liver enzymes; increases in the level of sugars in the blood and urine; increases in levels of uric acid and creatine phosphokinase in the blood; feeling more hungry; dizziness; restlessness; tremor; unusual movements (dyskinesias); constipation; dry mouth; rash; loss of strength; extreme tiredness; water retention leading to swelling of the hands, ankles or feet; fever, joint pain and sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Uncommon side effects (may affect up to 1 in 100 people) include hypersensitivity (e.g. swelling in the mouth and throat, itching, rash); diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma; seizures, usually associated with a history of seizures (epilepsy); muscle stiffness or spasms (including eye movements); problems with speech; slow heart rate; sensitivity to sunlight; bleeding from the nose; abdominal distension; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence or decrease in menstrual periods; and changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Rare side effects (may affect up to 1 in 1000 people) include lowering of normal body temperature; abnormal rhythms of the heart; sudden unexplained death; inflammation of the pancreas causing severe stomach pain, fever and sickness; liver disease appearing as yellowing of the skin and white parts of the eyes; muscle disease presenting as unexplained aches and pains; and prolonged and/or painful erection.

While taking olanzapine, elderly patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of patients.

In patients with Parkinson's disease ONTRIL may worsen the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ONTRIL

Keep out of the reach and sight of children.

Store below 25°C in a dry place.

Do not use ONTRIL tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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.