

Package leaflet: Information for the user

LEVOTUSS 30 mg/5 ml syrup levodropropizine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you develop any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse after 2 weeks of treatment.

What is in this leaflet

1. What Levotuss is and what it is used for
2. What you need to know before you take Levotuss
3. How to take Levotuss
4. Possible side effects
5. How to store Levotuss
6. Contents of the pack and other information

1. What Levotuss is and what it is used for

Levotuss contains levodropropizine as active ingredient, a substance that belongs to a group of medicines called cough suppressants.

This medicine is used for treating the symptoms of cough.

You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks of treatment.

2. What you need to know before you take Levotuss

Do not take Levotuss

- if you are allergic to levodropropizine or to any other ingredients of this medicine (listed in section 6);
- if you have a bronchial disease with a high production of mucus (bronchial hypersecretion);
- if you suffer, since birth, from a disorder of the lining of the respiratory tract that makes it difficult to eliminate mucus (Kartagener syndrome, ciliary dyskinesia).
- if you are pregnant or breastfeeding (see the sub-paragraph “Pregnancy and breastfeeding”).

Do not give this medicine to children under the age of two (see sub-paragraph “Children”).

Warning and precautions

Talk to your doctor or pharmacist before taking Levotuss:

- if you have severe reduction in kidney function (creatinine clearance below 35 ml/min);
- if you are elderly, because sensitivity to various medicines is altered in elderly people;
- if you are taking sedatives for the treatment of anxiety and if you are a particularly sensitive individual (see sub-paragraph “Other medicines and Levotuss”).

Cough medicines only treat the symptom of cough and should only be used until the underlying cause is diagnosed and/or treatment of the underlying problem takes effect.

Therefore, do not use the medicine for prolonged period of time. If no appreciable results are achieved after a short period of treatment (2 weeks), consult your doctor.

Levotuss does not contain gluten. It is therefore not contraindicated for people suffering from celiac disease.

Children

Do not give this medicine to children under the age of two (see sub-paragraph “Do not take Levotuss”).

Other medicines and Levotuss

Tell your doctor or pharmacist if you are taking, have recently taken or may be taking any other medicine.

Take this medicine with caution and tell your doctor if you are taking sedatives for the treatment of anxiety.

Pregnancy and breastfeeding

If you are pregnant, suspect that you are pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine. Consult your doctor also if you are breastfeeding.

Do not take Levotuss if you are certain or believe that you are pregnant or if you are breastfeeding (see paragraph “**Do not take Levotuss**”).

Avoid taking this medicine if you are planning to become pregnant.

Driving and using machines

This medicine may cause somnolence (see paragraph 4 “Possible side effects”). If you develop this symptom, avoid driving vehicles or using machinery.

Levotuss contains 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. This medicine contains 4 g of sucrose per dose (10 ml). This should be taken into account in patients with diabetes mellitus.

Levotuss contains methyl-para-hydroxybenzoate and propyl-para-hydroxybenzoate

The medicine contains methyl-para-hydroxybenzoate and propyl-para-hydroxybenzoate that are known for the possibility of causing urticaria. Para-hydroxybenzoates may generally cause delayed reactions such as contact dermatitis and rarely immediate reactions with urticaria and bronchospasm (tightening of the bronchi causing difficult breathing).

Levotuss contains sodium

This medicine contains less than 23 mg sodium per dose, that is to say essentially ‘sodium-free’.

3. How to take Levotuss

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take this medicine until the symptoms have disappeared. If after 2 weeks of treatment, you do not see any improvement, stop the treatment and talk to your doctor.

The recommended doses are

Adults: 10 ml of syrup up to 3 times daily with at least 6-hour-intervals.

Children over 2 years of age:

The recommended dose, based on body weight is:

- 3 ml of syrup if the child weighs between 10 and 20 kg,

- 5 ml of syrup if the child weighs between 20 and 30 kg.

The syrup can be administered up to 3 times daily, with at least 6-hour-intervals.

Warning: Do not exceed the recommended doses.

Method of administration

The package includes a measuring glass with 3, 5 and 10 ml notches.

To open the bottle press the cap firmly and turn anticlockwise

The syrup is to be drunk.

It is advisable to take the drug far away from meals, on an empty stomach.

If you take more Levotuss than you should

In the event of accidental intake of an excessive dose of Levotuss, immediately inform your doctor or contact your local hospital.

In most cases, the patients experienced abdominal pain and vomiting.

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

4. Possible side effects

Like all medicines, Levotuss can cause side effects, although not everybody develops them.

Most reactions are not severe and symptoms resolved after therapy discontinuation and, sometimes, after specific pharmacological treatment.

The frequency of the reported adverse reactions is unknown (the frequency cannot be determined based on the available data):

- mydriasis (dilation of the pupil of the eye), bilateral blindness (affecting both eyes);
- allergic and anaphylactoid reactions, palpebral oedema (swelling of the eyelid), angioneurotic oedema (swelling of the deep dermis and of the subcutaneous tissue that may also affect the mucous membranes), urticaria;
- irritability, somnolence, depersonalization (personality changes or personality disorders)
- syncope (transient loss of consciousness), dizziness, vertigo, tremors, paresthesia (abnormal feeling on the skin, tingling), tonic-clonic convulsions (grand mal) and mild epileptic attacks, hypoglycaemic coma (loss of consciousness caused by a severe drop in blood sugar levels);
- palpitations, tachycardia (rapid heartbeat), atrial bigeminy (irregular heartbeat);
- hypotension (low blood pressure);
- dyspnea (difficult breathing), cough, respiratory tract oedema (swelling);
- stomach pain, abdominal pain, nausea, vomiting, diarrhoea;
- cholestatic hepatitis (inflammation of the liver due to blocked biliary excretion);
- urticaria, erythema (skin redness), exanthema (rash), itching, angioedema (swelling of the face and mucous membranes), skin reactions, glossitis (inflammation of the tongue) and aphthous stomatitis (painful mouth sores);
- epidermiolysis (rare and potentially serious skin disease);
- weakness in the lower limbs;
- malaise, generalised oedema (swelling), asthenia (physical weakness).

Additional side effects in newborn babies breastfed by mothers who have taken Levodropropizine

An individual case was reported in a breastfed child who experienced somnolence, hypotonia (reduced muscle tone) and vomiting after the lactating mother took levodropropizine. Symptoms appeared after feeding and spontaneously resolved by discontinuing breast lactation for some feeds.

The compliance with the instructions contained in the package insert reduces the risk of undesirable effects.

Reporting 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. You can also report side effects directly via the national ADR reporting website: www.medicinesauthority.gov.mt/adrportal.

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

5. How to store Levotuss

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 package. The expiry date refers to the last day of that month. The expiry date applies to products stored correctly in their intact, original packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Levotuss contains

- The active substance is levodropropizine. 1 ml of solution contains 6 mg of levodropropizine
- The other ingredients are: **saccharose, methyl-para-hydroxybenzoate, propyl-para-hydroxybenzoate**, citric acid monohydrate, sodium hydroxide, cherry aroma, purified water

What Levotuss looks like and contents of the pack

Levotuss is a syrup for oral use and is available in bottles of 200 ml

Marketing authorization holder and manufacturer

Dompè farmaceutici S.p.A. – Via San Martino, 12, 20122 Milano (Italy)

Manufacturer

Dompé farmaceutici S.p.A.. - Via Campo di Pile, 67100 L'Aquila (Italy)

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