

HACTOSEC®

levodropropizine

TREATMENT FOR DRY, DISTURBING COUGH

EXCELLENT EFFICACY AND TOLERABILITY

No action on central nervous system

ADULTS	
10 ml (60 mg) syrup, 3 times daily, with at least a 6 hour interval.	
CHILDREN	
Patients between 10-20 kg	2 or 3 ml, 3 times daily
Patients between 20-30 kg	5 ml, 3 times daily
Patients over 30 kg	10 ml, 3 times daily

HIGHER EFFICACY THAN COMMON CENTRAL ACTING ANTITUSSIVES

“HACTOSEC® (levodropropizine) is an effective antitussive drug both in children and adults, showing statistically significant better outcomes versus central antitussive drugs in terms of overall efficacy in reducing cough intensity, frequency and night awakenings.”

Zanasi et al. Multidisciplinary Respiratory Medicine (2015). 10:19.

DAFRA PHARMA INTERNATIONAL

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Setting the Standard

www.dafrapharma.com

HACTOSEC®

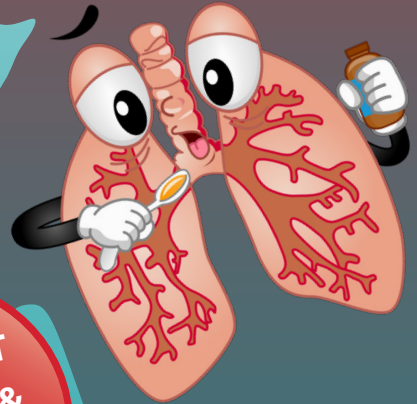
levodropropizine



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COMPOSITION

HACTOSEC® contains:

Levodropropizine, 6 mg per ml. Sucrose (0,5 g/ml), glycerol (0,1 g/ml), methylparaben (E218), propylparaben (E216), coffee flavor, cocoa flavor, citric acid, purified water.

HACTOSEC® comes in a dark coloured bottle with 150 ml of syrup, being a clear, colourless solution and a graduated measuring spoon indicating a quantity of 2ml, 3 ml and 5 ml.

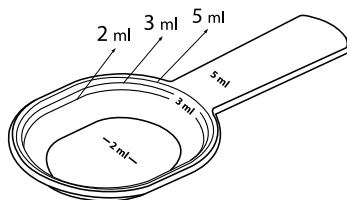
INDICATIONS

HACTOSEC® is a cough suppressant syrup to treat dry, disturbing cough (ATC code: R05DB27).

DOSAGE/MODE OF USE

It is recommended to take it away from meals. The time between administrations should be at least 6 hours.

A plastic spoon is included in the box. A full spoon contains 5 ml; filled up until the middle lining it contains 3 ml, until the bottom lining 2 ml.



Adults: 10 ml (60 mg) syrup, 3 times daily, with at least a 6 hour interval.

Children: only for children older than 2 years. Depending on the severity of symptoms: 1 to 2 mg per kilogram, maximum 3 times daily with an interval of at least 6 hours:

- patients between 10-20 kg:
2 or 3 ml, 3 times daily;
- patients between 20-30 kg:
5 ml, 3 times daily;
- patients over 30 kg:
10 ml , 3 times daily.

CONTRAINDICATIONS

HACTOSEC® is contraindicated:

- in patients with hypersensitivity to the active ingredient or one of the ingredients of this medication.

- when the patient is pregnant, trying to become pregnant or is breast feeding.
- If the patient suffers hepatic impairment
- If the patient has Kartagener's syndrome or any other disease characterised by respiratory system malfunctioning.
- This syrup should not be used in children below 2 years.

WARNINGS AND PRECAUTIONS

Caution before taking **HACTOSEC®**.

- In cases of severe kidney or liver failure, the benefit-risk ratio should be taken into consideration.
- The preservative ingredients in **HACTOSEC®** may cause allergic reactions (possibly delayed).
- Caution is advised in children and high-risk groups such as patients with liver disease or epilepsy.
- Caution is advised in diabetic patients (syrup contains 0.5 g sucrose per ml).

INTERACTIONS

- Patients sensitive to sedative medication should not take **HACTOSEC®** simultaneously with sedatives.
- Do not combine this syrup with a medicine having mucolytic or expectorant activity.

PREGNANCY/BREASTFEEDING

HACTOSEC® should not be used when pregnant, or planning to become pregnant, or when breast-feeding.

UNDESIRABLE EFFECTS

Most of the undesirable effects are mild and transient.

Which may include: lack of breath, fatigue, drowsiness, headache, tremor, discomfort,

paraesthesia, palpitations, increased heartbeat, hypotension, dyspnea, cough, swelling of the bronchi, nausea, vomiting, heartburn and abdominal pain, dyspepsia, diarrhea, allergic skin rashes, hypersensitivity reaction.

STORAGE

Store below 30°C in the original pack, protected from light. Keep out of the sight and reach of children.

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

HACTOSEC® is a prescription only medicine.

Marketing Authorisation Holder and Manufacturer: Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

Manufacturing facility:

Bilim Pharmaceuticals, GOSB 41480 Gebze, Kocaeli, Turkey.

For the complete SMPC, please visit www.dafrapharma.com