

PATIENT INFORMATION LEAFLET

DROPOLEV 30 mg + 2 mg/5 ml syrup

For oral use.

- **Active substance:** Each 5 ml (1 measuring spoon) syrup contains 30 mg levodropropizine and 2 mg chlorpheniramine maleate.
- **Excipients:** Sucrose, methyl paraben sodium (E219), propyl paraben sodium (E217), citric acid monohydrate, vanilla flavor, raspberry flavor, ponso 4R (E124) and deionized water.

Read this PATIENT INFORMATION LEAFLET carefully before you start using 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. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher or lower** dose other than the recommended to you.*

What is in this leaflet:

1. *What DROPOLEV is and what is it used for?*
2. *Before you use DROPOLEV*
3. *How to use DROPOLEV?*
4. *Possible side effects*
5. *How to store DROPOLEV?*

1. What DROPOLEV is and what is it used for?

- DROPOLEV is presented in a bottle of 150 ml with a measuring spoon of 5 ml.
- DROPOLEV contains levodropropizine and chlorpheniramine maleate as drug substances. It is used for the treatment of dry cough (a cough without phlegm) due to various causes.

2. Before you use DROPOLEV

DO NOT use DROPOLEV in the following cases

If;

- You are hypersensitivity to drug substances or any ingredients of DROPOLEV
- You are pregnant or you are breast-feeding
- You have a severe liver disease
- You have a disease that makes it difficult to remove phlegm (e.g. kartagener's syndrome and mucociliary function disorder)
- If you have taken monoamine oxidase inhibitor (MAOI) e.g. isocarboxazid, linezolid, phenelzine, tranylcypromine and drugs used for treatment of depression such as tricyclic antidepressants within the last 14 days, do not use DROPOLEV
- It is not recommended to use in children under 12 years

Take special care with DROPOLEV in the following conditions

If;

- You have severe kidney failure (creatinine clearance < 35 mL/min.)
- You have diabetes
- You have allergy
- You have gastric ulcer
- You have heart rhythm disorder
- You have epilepsy
- You have increased blood pressure or cardiovascular diseases
- You have prostate enlargement
- You have liver failure
- You have high eye pressure
- You have bronchitis, bronchiectasis (bronchial dilatation), asthma
- You have overactive thyroid dysfunction
- You are over 65 years old, do not use DROPOLEV without consulting your doctor

Cough medicines should not be used until the treatment of the underlying disease is provided and/or precipitating cause is detected.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using DROPOLEV with food and drink

Although any information that there is effect on the absorption when the DROPOLEV is taken with food is not available, it is advisable to take the medicine a time before or after the meal. It should not be used with alcohol.

Pregnancy

Ask your doctor or pharmacist for advice before using the medicine.

As DROPOLEV can cross the placental barrier, it can harm your baby. Therefore, do not use DROPOLEV during pregnancy.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before using the medicine.

DROPOLEV passes into breast milk. Therefore, do not use DROPOLEV during breast-feeding.

Driving and using machines

You must be very careful when driving and using machines because it may cause drowsiness.

Important information about some of the excipients of DROPOLEV

If you have been told by your doctor that you have an intolerance (intolerance) to some sugars because it contains sucrose, contact your doctor before taking this medicinal product.

Methyl paraben sodium (E219) and propyl paraben sodium (E217) in its content may cause allergic reactions (possibly delayed).

Contains ponso 4R (E124), which may cause allergic reactions.

Using with other medicines

Caution should be used in susceptible patients taking sedative medicines such as alprazolam, bromezepam, diazepam, clonazepam, clorazepate, chlordiazepoxide, buspirone, hydroxyzine, zolpidem.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use DROPOLEV?

- **Instructions for appropriate method and dose/frequency of administration:**

Use at the specified doses if not otherwise recommended by the doctor.

DROPOLEV is administered as 10 ml syrup (2 measuring spoons) 3 times a day with an interval of at least 6 hours in adults.

The drug should be taken until the cough disappears or according to the advice of a doctor provided that maximum 7-day treatment period is not exceeded. If the symptoms do not disappear within this period, the medication should be temporarily discontinued and a doctor should be consulted. Cough is a symptom of disease and therefore, the actual disease effect should be investigated and treated.

- **Route and method of administration:**

Although any information that there is effect on the absorption when the DROPOLEV is taken with food is not available, it is advisable to take the medicine a time before or after the meal.

DROPOLEV is only for oral use.

Drink syrup using a measuring spoon.

- **Different age groups:**

Use in children:

It is not recommended to use in children under 12 years.

5 ml three times per day in children weighing 20-30 kg (1 full spoon)

10 ml three times per day in children over 30 kg (2 full spoons)

Use in elderly:

The dose of DROPOLEV should be determined with caution in elderly patients.

- **Special populations:**

Kidney/Liver failure:

It should be used with caution taking into account the benefit-risk ratio in patients with severe renal insufficiency and hepatic insufficiency.

If you have the impression that the effect of DROPOLEV is too strong or too weak, talk to your doctor or pharmacist.

If you have taken more DROPOLEV than you should:

If you may have taken more DROPOLEV than you should, talk to a doctor or pharmacist.

If you forget to take DROPOLEV

Do not take double dose to balance the missed doses.

If you stop taking DROPOLEV

Not applicable.

4. Possible side effects

Like all medicines, DROPOLEV may cause side effects in some patients who are sensitive to the substances contained in DROPOLEV.

Stop taking DROPOLEV and tell your doctor straight away or seek the nearest hospital emergency department if you experience any of the following:

Difficulty in breathing, swelling in the face, lips, tongue or throat, sudden blood pressure decrease, widespread and severe redness, itching, urticaria (hives).

These are very serious side effects.

If you have them, you may have had a serious allergic reaction to DROPOLEV. There may be an urgent need for medical intervention or hospitalization.

Side effects were listed as shown in the following categories:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: it cannot be estimated from the available data.

Very common

- Sedation (allayment)
- Somnolence

Common

- Exhaustion
- Constipation
- Vomiting

- Dry mouth
- Attention deficit
- Abnormal coordination
- Dizziness

Rare

- Urinary retention

Very rare

- Hypersensitivity reaction
- Fatigue-asthenia, weakness
- Lethargy
- Headache
- Dizziness due to impaired balance (vertigo)
- Tremor
- Feeling of numbness (paresthesia)
- Palpitation
- Low blood pressure (hypotension)
- Shortness of breath (dyspnea)
- Cough
- Edema in the respiratory tract
- Nausea, heartburn and pain
- Dyspepsia
- Diarrhea
- Nervousness
- Drowsiness, loss of self
- Skin redness (erythema)
- Skin rash (exanthema)
- Skin reactions where soft tissue in hands and feet, lips, genital organs and eyelids have deeper and wider edema (angioedema)
- Weakness in legs
- Temporary visual loss and enlargement of pupils
- Sara-like seizure (epilepsy)

Unknown

- Severe allergic reactions (anaphylactic reactions)
- Darkening of bronchial secretions
- Insomnia
- Increased excitability
- Anxiety
- Clouding of consciousness (confusion)
- Anger easily (irritability)
- Nightmares
- Depression
- Common redness and peeling of the skin (exfoliative dermatitis)
- Redness
- Sensitivity to light (photosensitivity)

- Hemolytic anemia
- Blood disorders (blood dyscrasias)
- Loss of appetite (anorexia)
- Blurred vision
- Tinnitus
- Hepatitis, jaundice
- Muscle twitching and muscle weakness
- Chest pain and tightness
- Irregular heartbeat (arrhythmia)

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5.How to store DROPOLEV?

Keep out of the sight and reach of children and store in the original package.

Store at room temperature below 25°C protected from light.

Use in accordance with the expiry date.

Do not use DROPOLEV after the expiry date on packaging.

Do not use DROPOLEV if you notice any damage on product and/or packaging.

Marketing authorization holder:

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