

PATIENT INFORMATION LEAFLET

DROPOLEV 60 mg/ml oral drops

For oral use.

- **Active substance(s):** Each 1 ml (20 drops) solution contains 60 mg levodropropizine.
- **Excipient(s):** Contains methyl paraben sodium (E219), propylene glycol, sucrose, citric acid monohydrate, sodium saccharine, mint flavor, aniseed flavor, FD&C yellow No.6 (E110), taste masking aroma 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this leaflet:

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

- DROPOLEV is a solution presented in a bottle of 30 ml with dropper cap.
- DROPOLEV contains levodropropizine as active substance.
- It is used to relieve dry cough (a cough without phlegm) due to various causes.

2. Before you use DROPOLEV

Do not use DROPOLEV in the following conditions

If;

- You are allergic (hypersensitive) to levodropropizine or any of the other ingredients of DROPOLEV
- You are pregnant or you are breastfeeding
- 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)

TAKE SPECIAL CARE WITH DROPOLEV in the following conditions

If;

- You have severe kidney failure (creatinine clearance <35 ml/min.)
- You have diabetes
- You are over 65 years old, do not use DROPOLEV without consulting your doctor.

DROPOLEV should not be used in long term treatments.

Cough medicines should not be used until the treatment of the underlying disease is provided and/or precipitating cause is detected. Consult your doctor if you have not had a clear result after a short course of treatment.

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

Using DROPOLEV with food and drink

It is recommended to take it a time before or after meal although there is no data on the effect of DROPOLEV ORAL DROPS taken with food on the absorption.

Pregnancy

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

DROPOLEV can harm your baby because it passes across the placental barrier. Therefore, do not use DROPOLEV during pregnancy.

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

Breastfeeding

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

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

Effects on ability to drive and use machines

You should be very careful when driving and using machine, as it may cause drowsiness.

Important information about some of the ingredients of DROPOLEV

Due to on it contains sucrose, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DROPOLEV.

This medicinal product contains less than 1 mmol (23 mg) of sodium per each 1 ml, i.e. essentially “sodium-free”.

It contains colorant FD&C yellow No.6 (E110) which may cause allergic reactions

It contains methyl paraben sodium (E219) which may cause allergic reactions (possibly delayed)

Using with other medicines

Caution should be taken 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:**

Take specified dosage unless recommended otherwise by your doctor.

DROPOLEV is administered as 20 drops (60 mg levodropropizine, 1 drop is 0.05 mL) three times a day and at least 6 hours apart in adults.

It 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 the disease, so the cause of the actual disease should be investigated and treated.

- **Route and method of administration:**

It is recommended to take it a time before or after meal although there is no data on the effect of DROPOLEV taken with food on the absorption.

DROPOLEV is only for oral use.

Drops should preferably be taken with half a glass of water.

- **Different age groups:**

Use in children:

It is used for children over 2 years.

It is used 3 times a day and at least 6 hours apart as indicated below:

Weight (kg)	Number of drops in each use	Weight (kg)	Number of drops in each use
7-10	3	29-31	10
11-13	4	32-34	11
14-16	5	35-37	12
17-19	6	38-40	13
20-22	7	41-43	14
23-25	8	44-46	15
26-28	9	>46	20

Use in elderly:

The dose of DROPOLEV should be determined carefully in elderly patients.

- **Special populations:**

Kidney/Liver failure:

It should be used with caution considering the benefit-risk ratio in cases of severe kidney failure.

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 used 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 use DROPOLEV:

Do not use a double dose to make up for a forgotten dose.

If you stop using DROPOLEV:

None.

4. Possible side effects?

Like all medicines, side effects can occur in people sensitive to the contents of DROPOLEV.

If any of the following occur stop using DROPOLEV and IMMEDIATELY inform your doctor or go to the nearest emergency department:

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

These are all very serious side effects.

If you have any of them, this means you have serious allergy to DROPOLEV. You may need emergency medical care 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.

If any of the following occur immediately inform your doctor or go to the nearest emergency department:

Very rare (may be seen less than 1 in 10000 patients)

- Hypersensitivity reactions
- Fatigue, exhaustion
- Lethargy
- Headache
- Dizziness due to impaired balance (vertigo)
- Tremor
- Palpitation
- Low blood pressure
- Shortness of breath (dyspnea)
- Cough
- Edema in the respiratory tract
- Nausea
- Tongue inflammation, mouth sores
- Vomiting
- Heartburn and pain
- Decrease in blood sugar level
- Dyspepsia
- Diarrhea
- Nervousness
- Drowsiness

- Loss of self
- Skin reactions where hands and feet, lips, genital organs and soft tissue in eyelids have deeper and wider edema (angioedema)
- Weakness in legs
- Temporary visual loss and enlargement of pupils,
- Sara-like seizure (epilepsy)

These are all serious side effects. They may be require emergency medical treatment. These serious side effects occur very rarely.

If you notice any side effects not mentioned in this leaflet inform your doctor or pharmacist.

5. How to store DROPOLEV

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

Store in room temperature under 25°C protecting from light.

Use in accordance with expiry date.

Do not use DROPOLEV after the expiry date which is stated on the package.

Do not use DROPOLEV if you notice any damage to the product and/or package.

Marketing Authorization Holder:

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