

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dextrolag® Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml syrup contains Dextromethorphan Hydrobromide 10 mg; Guaifenesin 100 mg; Chlorphenamine maleate 2 mg; Ammonium Chloride 25 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cough syrup

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS

Dextrolag belongs to a group of medicines called cough expectorants and cough suppressants. This medicine contains the active ingredients: Guaifenesin and Ammonium Chloride, that work by changing an unproductive cough to a cough that is more productive and less frequent; dextromethorphan that works by providing relief from persistent dry irritant coughs; Chlorphenamine maleate an antihistamine which can help to relieve the symptoms of some allergies.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

Posology

Adults, the elderly and children over 12 years: Take 10 ml - 40 ml daily, as required.

Children (over 6 years): 2.5 ml - 5 ml , twice or four times daily according to the age and condition of the child.

Children (under 6 years): Do not use.

Do not exceed the stated dose. No more than four doses should be taken in 24 hours.

Method of Administration:

Dextrolag Sryup is for oral use.

The syrup may be administered alone or diluted in a small amount of liquid (water, milk or fruit juice), preferably after meals.

4.3. CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

Taking a prescription monoamine oxidase inhibitor (MAOI), a selective serotonin reuptake inhibitor (SSRI), or other medications for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the medication. If you are not sure if your prescription medication contains one of these medicines, ask a doctor or pharmacist before taking this product.

4.4. SPECIAL WARNINGS & PRECAUTIONS FOR USE

Patients suffering from chronic cough as occurs with smoking, asthma or patients suffering from an acute asthma attack, or where cough is accompanied by a fever, rash or persistent headache should be advised to consult a Healthcare Professional before use.

- You have very high blood pressure, heart disease, epilepsy, glaucoma, enlarged prostate, liver disease, kidney disease, bronchitis or bronchiectasis.
- You are taking any prescribed medicines; particularly phenytoin (for epilepsy) or medicines for anxiety or to help you to sleep.
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Only use this medicine as described.

Cases of dextromethorphan abuse have been reported. Caution is particularly recommended for adolescents and young adults as well as in patients with a history of drug abuse or psychoactive substances.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.

Patients with rare hereditary galactose intolerance, the lapp lactase deficiency or glucose galactose malabsorption should not take this medicine.

Dextrolag Syrup contains 2.5 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus.

This medicine may interfere with the results of some urine tests. If you are having any urine tests, tell the doctor or hospital staff that you are taking this medicine.

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Do not take if you are taking any of the following medicines, or have done so in the last 14 days:

- A prescription monoamine oxidase inhibitor (MAOI), used to treat depression and Parkinson's disease.
- A selective serotonin reuptake inhibitor (SSRI), used to treat depression and anxiety.
- Any other medication for depression, psychiatric, or emotional conditions, or Parkinson's disease.

Dextrolag Syrup may interact with the following drugs and products:

- Quinidine or Amiodarone (or any other medicines which are used to treat heart conditions).
- Terbinafine used to treat fungal infections.
- Cinacalcet used to treat an overactive parathyroid gland.
- Methadone used for severe pain

Dextrolag may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g nausea, vomiting, diarrhoea).

If you are not sure if your prescription medicine contains one of these drugs, ask a doctor or pharmacist before taking this product.

4.6. FERTILITY ,PREGNANCY AND LACTATION

The usual precautions regarding the use of drugs during pregnancy should be observed. Please talk to your doctor before taking this medicine if you are pregnant or breastfeeding

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It may be an offence to drive when taking this medicine.
- However, you would not be committing an offence if The medicine has been taken to treat a medical problem and
- You have taken it according to the information provided with the medicine and
- It was not affecting your ability to drive safely

4.8. UNDESIRABLE EFFECTS

Like all medicines, Dextrolag can cause side effects, although not everybody gets them. Side effects with Dextrolag are rare. However, some susceptible individuals may experience unwanted side effects.

If you experience any of the following side effects mentioned below or any other side effects, STOP taking this medicine immediately and contact your doctor:

- Allergic reactions. Symptoms could include itchy skin or rashes, difficulty breathing, faster heart rate, swelling of the face or throat.
- Stomach upset.
- Dizziness, drowsiness, mental confusion, headache or blurred vision.
- Unknown frequency: dependence and addiction (see section “How do I know if I am addicted?”).

Other possible side effects:

- Feeling sick (nausea), loss of appetite, indigestion, feeling or being sick (vomiting), diarrhoea, tummy pain or dry mouth.

- Low blood pressure (you may feel faint) or changes in heart rhythm
- Chest tightness or thickening of phlegm.
- Skin peeling, itchy rash and sensitivity to the sun.
- Ringing in the ears.
- Twitching, muscular weakness and abnormal co-ordination.
- Confusion, excitability, irritability, low mood or nightmares.
- Children may become excited.

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

Drug Withdrawal

When you stop taking Dextrolag, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

4.9 OVERDOSE

In case of overdosage the symptoms mentioned under side effects worsen. Other signs of over dosage are perspiration , cardiac palpitation, blurred vision, state of excitation . Severe side effect from dextromethorphan and guaifenesin are usually only seen in patients who have taken very high doses. These patients should be induced immediate medical attention.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Cough suppressant

Dextrolag is a non-narcotic, fixed combination product, in the form of syrup with antitussive and expectorant properties. Dextromethorphan Hydrobromide is one of the most potent synthetic antitussives. Its activity as a cough suppressant is practically the same as that of codeine. It is however , devoid of all the other pharmacological properties of codeine and of its side effects , in particular its habit-forming property.

Guaifenesin and Ammonium Chloride, that work by changing an unproductive cough to a cough that is more productive and less frequent.

Chlorphenamine maleate an antihistamine which can help to relieve the symptoms of some allergies.

5.2. Preclinical Safety Data

There is no relevant information additional to that already contained elsewhere in the SmPC or of relevance to the prescriber.

6. Pharmaceutical Particulars:

6.1. List of excipients

Sodium Benzoate, Sucrose, Saccharin Sodium, Monosodium Glutamate, carmoisine, Raspberry flavor.

The bottle contains 100 ml.

6.2. Incompatibilities:

Not applicable

6.3. Shelf life:

36 Months

6.4. Special precautions for storage:

Keep out of the sight and reach of children.

Do not use this medicine after the 'EXP' date shown on the pack.

Store at room temperature (15-25°C) in the original pack.

6.5. Nature & contents of container:

125ml amber colored glass bottle sealed with child resistant cap.

7. MARKETING AUTHORISATION HOLDER

Lagap SA, UAE

Po. Box 46222

Abu Dhabi, UAE

(A division of Lagap Switzerland)

8. MARKETING AUTHORISATION NUMBER(S)

05265/07222/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of Approval : 11-08-2020