

Patient package insert in accordance with the Pharmacist's Regulations (Preparations) – 1986

Ages 2 to 6 years old: This medication is sold with a doctor's prescription only.

Age 6 or older: This medication is sold without a doctor's prescription.

Alcinal Syrup

Composition: Each 5 ml contains:
Dextromethorphan Hydrobromide 7.88 mg
Chlorpheniramine Maleate 1.00 mg
Guaiphenesin 105.00 mg

For a list of the inactive ingredients in this preparation see Section 6 – "Additional information".

Read this leaflet carefully in its entirety before using this medication. This leaflet contains concise information about the medication. If you have further questions, refer to a doctor or pharmacist.

This medication is not intended for administration to children and infants under the age of two. For children under the age of 6: administration of this medication requires a doctor's prescription.

You must use the medication properly. If you need further information, consult a pharmacist.

Consult a doctor if the disease symptoms worsen or do not improve after 7 days.

1. What is this medication intended for?

This medication is intended for the alleviation of coughing and nasal congestion associated with colds.

Therapeutic group:

Dextromethorphan – cough suppressant,
Chlorpheniramine – antihistamine,
Guaiphenesin – expectorant.

2. Before using this medication

Do not take this medication if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients included in the medication.
- You are sensitive to antihistamines. Symptoms include: a rash, difficulty breathing, and swelling of the lips or face.
- Do not use for infants under the age of two.
- You are currently taking medication that belongs to the group of MAO inhibitors, such as antidepressants or medications for the treatment of Parkinson's disease, and for two weeks after completing treatment with medications belonging to this group.
- Do not use during an asthma attack.

Consult a doctor before beginning treatment if:

- You are pregnant or breastfeeding.
- You are suffering, or have suffered in the past, from impaired function of the respiratory system [e.g. asthma, bronchitis, or bronchial dilation (bronchiectasis)].
- You are suffering, or have suffered in the past, from impaired function of the heart and/or vascular system.
- You are suffering, or have suffered in the past, from impaired function of the eyes (e.g. glaucoma).
- You are suffering, or have suffered in the past, from impaired function of the liver.
- You are suffering, or have suffered in the past, from impaired function of the kidneys / urinary tract (difficulty urinating), digestive system (e.g. an ulcer), or intestinal blockage.
- You are suffering, or have suffered in the past, from impaired function of the thyroid gland.
- You are suffering, or have suffered in the past, from impaired function of the blood system, e.g. coagulation.
- You are suffering, or have suffered in the past, from impaired function of the prostate gland.
- You suffer from diabetes.
- You suffer from high blood pressure.
- You suffer from the rare blood disease called porphyria (a genetic disease).
- You suffer from epilepsy.
- If the cough is accompanied by fever, itching, or headache.
- You are suffering from a prolonged or chronic cough, accompanied by conditions such as: smoking, asthma, chronic bronchitis, pulmonary emphysema; or if the cough is accompanied by excessive production of sputum.

Special warnings regarding the use of this medication:

- Do not use this medicine frequently or for a prolonged period of time without consulting a doctor.
- If you are sensitive to any food or medications, you must inform the doctor before taking this medication.
- If you are about to undergo surgery (including dental surgery) or any other procedure involving anesthesia, the use of this medication should be reported to the anesthesiologist.
- Inform the doctor if you are about to undergo any allergy skin tests or a test for hydroxyzine, amylase or prolactin, since treatment with this medication may affect the results.
- The elderly must be under medical supervision in light of the fact that they are more sensitive to the side effects.
- **If you are taking, or have recently taken another medication, including non-prescription medications or food supplements, inform the doctor or pharmacist.** It is especially important to inform the doctor or pharmacist if you are taking the following medications:
 - Medications that affect the central nervous system, [e.g. sedatives, sleep medications, Parkinson's medications, anti-epileptics (e.g. phenytoin)].
 - Antidepressants.
 - Other cough or cold medications.
 - Anticholinergic drugs or drugs with anticholinergic activity (e.g. stomach antispasmodics).
 - Antidepressants that belong to the group of MAO inhibitors. If you are taking a medication that belongs to this group, do not use Alcinal New Syrup. You may use this syrup two weeks after completing treatment with a medication from this group.
 - Strong painkillers, such as narcotic analgesics, e.g. codeine.
 - A different antihistamine.
 - Asthma medications.
 - Medications used to treat mental illness.
 - Atropine.

Use of this medication and food:

This medication should be taken during a meal, with water or milk.

Do not drink wine or other alcoholic beverages while under treatment with this medication.

Pregnancy and breastfeeding:

Do not take this medication if you are pregnant or breastfeeding.

Use of this medication and driving:

Use of this medication may impair alertness and cause drowsiness; therefore, caution should be exercised while driving a car, when operating dangerous machinery, and during any other activity that requires alertness. Children should be cautioned against engaging in activities such as riding bicycles, playing near roads, and the like.

Important information about some of this medication's ingredients:

This medication contains preservatives: methylparaben (5 mg) and propylparaben (1 mg), which may cause allergic reactions (delayed reactions are possible).

This medication contains a small quantity of alcohol (ethanol). Each 5 ml contains 20 mg alcohol (the total amount in 115 ml is 460 mg alcohol at a concentration of 0.48%).

In addition, each 5 ml contains: 2,300 mg sucrose and 120 mg sodium. If you have been told by your doctor to avoid consuming salt or alcohol, or that you have an intolerance to certain sugars, consult your doctor before taking this medication.

3. How to use this medication:

Check with the doctor or with the pharmacist if you are unsure.

This medicine is not intended for administration to children and infants under the age of two.

For children aged 2 to 6, administration of this medication requires a doctor's prescription.

For children aged 6 or older, the medication will be sold without a doctor's prescription and will be dispensed by the pharmacist alone.

Recommended dosage unless otherwise prescribed by a doctor:

Children aged 2-6 years: according to doctor's prescription only.

Children aged 6-12 years: 5-10 ml, 3-4 times a day.

Adults and children over the age of 12: 10-20 ml, 3-4 times a day.

Do not exceed the recommended dosage.

If there is no improvement in your condition within 7 days, consult a doctor.

If you forget to take this medication at the required time, do not take a double dose. Take the next dose at the usual time and consult a doctor. Take the medicine during a meal with water or milk.

Care must be taken to measure the dose using the measuring cup provided in the package.

If you have accidentally taken an overdose, or if a child has accidentally swallowed the medication, refer immediately to a doctor or a hospital emergency room and bring the medication package with you. Do not take medications in the dark! Check the label and the dose each time you take your medication. Wear glasses if you need them.

If you have further questions regarding the use of this medication, consult a doctor or pharmacist.

4. Side effects

As with any medication, use of this medication may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

Consult a doctor if the following side effects are prolonged or especially troublesome:

- Gastrointestinal discomfort, mild drowsiness.

Side effects:

Dry mouth, drowsiness, dizziness, headaches, spasms, blurred vision, stomach aches, sleep disorders, difficulty urinating, sweating, skin rash, sensitivity to sunlight, allergic reactions, indigestion, loss of appetite, tremors, muscle pain or weakness, movement and coordination disorders, tingling, changes in heart rate, palpitations, low blood pressure, ringing in the ears, hair loss, blood disorders such as anemia, fatigue, liver problems (which may cause yellowing of the skin or the eyes), chest pains, cough, phlegm in the chest – these may be caused by viscous secretions of the bronchi to the lungs, difficulty concentrating, irritability, depression, hyperactivity in children, confusion in the elderly.

Side effects and drug interactions in children and infants: Parents must inform the attending physician of any side effects and of any other medication being administered to the child!

If any of the side effects worsen, or if you experience any side effects not mentioned in this leaflet, consult a doctor or pharmacist.

Side effects may be reported to the Ministry of Health by clicking the link "Report of side effects resulting from the use of medications" on the homepage of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects.

5. How should the medication be stored?

Avoid poisoning! This medication, and all other medications, must be stored in a safe place out of the reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor!

Do not use this medication after the expiry date printed on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C.

After opening the bottle for the first time, the medication may only be used for 28 days, provided that it has not reached the expiry date. Write the date that the bottle was first opened on the package.

Even under the recommended packaging / storage conditions, medications may be kept for a limited period of time only. Please note the expiry date of the preparation! The expiry date refers to the last day of that month.

6. Additional information

In addition to the active ingredients, the preparation also contains the following inactive ingredients:

Sucrose, alcohol, methylparaben, propylparaben, citric acid, glycerin, sodium saccharin, sodium cyclamate, ponceau 4R, supra blue, black cherry, aroma cacao, purified water.

What does the medication look like and what are the contents of the package?

A bottle containing 115 ml clear syrup with a red color and a slight cherry scent.

Manufacturer and license holder:

Rekah Pharmaceutical Products Ltd., 30 Hamelacha Street, Holon.

This leaflet was reviewed and approved by the Ministry of Health in: June 2015.

Medication registration number in the national medication registry of the Ministry of Health: 11485-29581-00