PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

Reolin Effervescent Tablets 200 mg

Active ingredient:
Each effervescent tablet contains:
Acetylcysteine 200 mg
- List of inactive ingredients in the preparation: See "Further information" section (section 6)

Carefully read the leaflet in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
- The medicine is intended for adults and children above two years of age. Below 2 years of age, refer to the doctor.
- Use this medicine properly. Consult a pharmacist if you need further information.
- Refer to a doctor if the signs of the ailment (symptoms) worsen or do not improve after 4 to 5 days from starting treatment with the medicine.

1. WHAT IS THE MEDICINE INTENDED FOR:

Reduces the viscosity of sputum and eases its excretion in respiratory tract disorders.

Therapeutic group - sputum viscosity reducer (mucolytics)

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
- If you are sensitive (allergic) to the active ingredient (acetylcysteine) or to any of the ingredients contained in the medicine (see a detailed list of the inactive ingredients in the "Further Information" section)
- Do not use this medicine in children under the age of 2, due to the high level of active ingredient

Special warnings regarding use of the medicine
- Very rarely, severe skin effects, such as Stevens-Johnson syndrome and Lyell's syndrome, may occur after administration of acetylcysteine.
  If you notice any changes in the skin and/or mucous membranes, discontinue use of Reolin immediately and refer to a doctor immediately.
- If you are suffering from asthma or are suffering, or have suffered in the past, from a gastric or intestinal ulcer, consult the doctor before use.
- Exercise extra caution and consult the doctor before commencing use of Reolin in patients with an intolerance to histamine. Avoid prolonged treatment in such patients, since Reolin has an effect on histamine metabolism and therefore, may cause intolerance symptoms (e.g., headaches, runny nose and itching).

❗If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to tell the doctor or pharmacist if you are taking:
- medicines to relieve/prevent cough - use of these medicines in combination with Reolin may cause congestion in the lungs due to a limited cough reflex; therefore, use this medicinal combination with great caution.

Consult the doctor before combined use with these medicines:
- antibiotics apart from Cefixim and Loracarbef. Reolin weakens the effect of antibiotics, especially from the following groups: tetracyclins, aminoglycosides and penicillins.
  Take antibiotics at least two hours after taking Reolin.

❗Taking Reolin and food
Reolin can be taken with or after food.

❗Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant, are planning to become pregnant or are breastfeeding, consult the doctor before using Reolin.

❗Driving and operating machines
No dangerous effect on driving or operation of machines is expected.

❗Important information regarding some of the ingredients of the medicine:
Reolin contains sodium, 99 mg per tablet. If you are on a low-salt diet, take the amount of sodium in the medicine into consideration.
The preparation contains lactose and may cause allergy in people who are sensitive to lactose.

3. HOW SHOULD THE MEDICINE BE USED?

Check with the doctor or pharmacist if you are uncertain.
- The generally accepted dosage is:
  Accepted dosage in adults and children above 14 years of age:
  One tablet, 2-3 times a day.
  Accepted dosage in children from 6 to 14 years of age:
  One tablet, twice a day.
  Accepted dosage in children from 2 to 5 years of age:
  Half a tablet, 2-3 times a day.
  Do not exceed the recommended dose.
- Manner of administration: **Do not swallow,** dissolve this tablet in a glass of cold or warm water before taking it and drink it as soon as it has dissolved. Reolin can be taken with or after food.
- Consult a doctor or pharmacist if you feel that the effect of the medicine is too strong or too weak.
- Treatment duration: refer to a doctor if the signs of the ailment (symptoms) worsen or do not improve after 4 to 5 days from starting treatment with the medicine.

If you forget to take this medicine at the specified time, continue taking the medicine as instructed. Do not take a double dose.
Even if there is an improvement in your health, do not stop treatment with the medicine or change the dosage without consulting the doctor or pharmacist.

If you accidentally took a higher dosage, you may experience effects of irritation in the digestive system (e.g., abdominal pains, nausea, vomiting, diarrhea).
No severe side effects or toxicity have been observed, even at especially high dosages.
If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
If you forget to take the medicine at the designated time, continue taking the medicine as instructed. Do not take a double dose.
Even if there is an improvement in your health, do not stop treatment with the medicine or change the dosage without consulting the doctor or pharmacist.
- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
- If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Reolin Effervescent Tablets may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not get any of them.

Effects that occur infrequently:
Headaches, fever, allergic reaction: stinging sensation in the skin, rash, itching, breathlessness, rapid or accelerated pulse, reduced blood pressure. Inflammation of the oral mucosa, abdominal pains, nausea, vomiting and diarrhea.

Effects that occur rarely:
Breathlessness, bronchospasms - primarily in patients suffering from asthma.

Effects that occur very rarely:
An association between use of Reolin and appearance of hematomas has been reported; it may be related to hypersensitivity reactions to the preparation.

If a side effect occurs, if any of the side effects worsens, or if you experience side effects not mentioned in the leaflet, consult the doctor.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects,
Or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless clearly indicated by the doctor.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Attention: After first opening the tube, the medicine should be used within two years from the day of opening. In any case, however, do not use after the expiry date that appears on the package.
- Store in the original package at a temperature below 25°C, in a dry place.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Sodium 99.00 mg
Lactose 75.00 mg
Cyclamate 17.70 mg
Saccharin 3.55 mg
Inactive ingredients:
Sodium Carbonate Anhydrous, Lactose Anhydrous, Mannitol, Flavour Lemon "AU Code 132", Sodium Cyclamate, Saccharin Sodium, Sodium Citrate Dihydrate, Citric Acid Anhydrous, Sodium Hydrogen Carbonate.
What the medicine looks like and contents of the pack - 30 white tablets in a hard tube.
The tube is packed in an outer carton.
License holder and address: Pharmalogic LTD., P.O.B. 3838, Petah-Tikva 4951623.
Manufacturer and address: Hochland Pharma, Wolfratshausen, Germany.
This leaflet was checked and approved by the Ministry of Health in September 2016.
Drug Registration Number in the National Drug Registry of the Ministry of Health: 127-37-3062600