

REXOM UNIZET SYRUP

Diphenhydramine Hydrochloride/Bromhexine Hydrochloride/Ammonium Chloride (8mg/4mg/100mg per 5ml)

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What REXOM UNIZET is used for

For productive cough and alleviation of nasal stuffiness, sneezing, lachrymation (flow of tears), mucolytic (to dissolve thick mucus and relieve respiratory difficulties) and bronchial congestion.

How REXOM UNIZET works

Diphenhydramine is an antihistamine used to treat sneezing, runny nose, itching and other symptoms of allergies and the common cold.

Bromhexine is a mucolytic agent which works by thinning the mucus in the airways, thus making the mucus less sticky and it facilitates the removal of the mucus.

Ammonium chloride used as reflux expectorant.

Before you use REXOM UNIZET

- When you must not use it

Do not use it when you have:

- Hypersensitivity to any of the ingredients.
- Individual on monoamine oxidase inhibitor therapy within 14 days.
- Diphenhydramine should not be given to premature infants and neonates, they have increased susceptibility to antimuscarinic effect (eg: dry mouth, blurred vision, discomfort to the eyes, heart rhythm disorder, difficulty in urination, elevated body temperature and eye disease that may cause vision loss).
- Children below 2 years old.

Pregnancy and lactation

- It is recommended that REXOM UNIZET Syrup should not be used during

pregnancy particularly as the safety of REXOM UNIZET Syrup in human pregnancy is not established.

- It is recommended REXOM UNIZET SYRUP should not be used during lactation particularly as the safety of REXOM UNIZET SYRUP during lactation is not established.

-Before you start to use it

When used for treatment of cough and cold:

- (a) Not to be used in children less than 2 years of age
- (b) To be used with caution and doctor's/pharmacist's advice in children 2 to 6 years of age.

REXOM UNIZET should be used with caution in conditions with closed angle glaucoma (increased pressure inside the eyes), urinary retention, prostatic hyperplasia (enlargement of prostate) and pyloroduodenal obstruction (gastric outflow obstruction).

-Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

REXOM UNIZET may interact with:

- Additive CNS depressant effects with alcohol and other CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics.
- Additive antimuscarinic effects with other drugs of similar properties such as atropine and some antidepressants.
- Individual taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment as there is a risk of serotonin syndrome.
- Diphenhydramine can inhibit the oxidative metabolism of some drugs.
- Diphenhydramine may enhance the effects of ephedrine.
- Diphenhydramine may mask the response of the skin to allergenic skin tests and also the ototoxic symptoms associated with certain antibiotics.

How to use REXOM UNIZET

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults: 10 ml (2 teaspoonfuls) of syrup 3 times a day, not to exceed 6 tsp in 24 hrs.

Children aged 6-12 years: 5 ml (1 teaspoonful) of syrup 3 times a day. Maximum daily dose: 15 ml syrup.

Not to be used in children less than 2 years of age. To be used with caution and doctor's/pharmacist's advice in children 2 to 6 years of age.

-When to use it

Use as directed by your doctor or pharmacist. Not to be used in children less than 2 years of age. To be used with caution and doctor's/pharmacist's advice in children 2 to 6 years of age.

-How long to use it

Continue taking REXOM UNIZET as your doctor recommended.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose include those due to diphenhydramine or menthol (drowsiness, dizziness, ataxia (lack of muscle coordination), anti-cholinergic

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effects, pyrexia (fever), headaches, convulsions, hallucinations, excitement and respiratory depression).

Treatment consists of gastric lavage and aspiration. Administration of activated charcoal may help. Other symptomatic and supportive measures should be provided.

While you are using REXOM UNIZET

-Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking REXOM UNIZET.
- Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give REXOM UNIZET to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

This product may cause drowsiness. Do not drive or operate machinery.

Side effects

REXOM UNIZET SYRUP may cause severe allergy and serious skin reactions. Stop using REXOM UNIZET SYRUP and seek medical assistance immediately if you experience any of the following symptoms:

- 1) severe allergy: breathing difficulties, light headedness, skin swellings or rash.
- 2) severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation.

Common side effects include:

- CNS effects such as nervous drowsiness (usually diminishes within a few days), paradoxical stimulation (when medical treatment, usually a drug, has the opposite effect to that which would normally be expected), nervous headache (stand-alone illnesses caused directly by the

overactivity of, or problems with, structures in the head that are pain-sensitive), nervous psychomotor impairment (a slowing-down of thought and a reduction of physical movements in an individual).

- Antimuscarinic effects such as urinary retention, dry mouth, blurred vision, gastrointestinal disturbances and thickened respiratory tract secretions.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website <http://www.npra.gov.my>

(Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of REXOM UNIZET

-Storage

Keep container tightly closed protected from light. Store below 30°C.

Keep medicine out of reach of children.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

-What it looks like

Red colour liquid with orange flavor.

-Ingredients

-Active ingredient

Each 5ml contains
Diphenhydramine Hydrochloride,
Bromhexine Hydrochloride,
Ammonium Chloride.

-Inactive ingredients

Levomenthol, Sodium Benzoate, Sodium Citrate, Citric Acid Anhydrous, Saccharin Sodium, Glycerin, Tartaric acid, Propylene glycol, Sucrose, Orange flavor, Ponceau 4R and purified water.

-MAL number:

Manufacturer and Product Registration Holder

KCK Pharmaceutical Industries Sdn. Bhd.
Plot 61, Bayan Lepas Industrial Park
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11900 Pulau Pinang,
Malaysia.

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