PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986 This medicine is dispensed without a doctor's prescription

MUCOLESS Solution

Composition: Each 1 ml (20 drops) contains: Bromhexine HCl 2 mg

For the list of inactive ingredients: See section 6 "Further information" Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine was prescribed to treat your illness. Do not forward it to others. It may harm them even if it looks like they are in a similar medical condition.

This medicine is not recommended to children and infants below 2 years of age without a doctor recommendation.

What is this medicine intended for?

Reduces the viscosity of mucus and phlegm. The medicine is intended for the relief of mucus secretion during cough in situations where mucus is accumulated in the respiratory system. The medicine can be used also by inhalation.

Therapeutic Group: Reduce the viscosity of mucus and phlegm.

Before using this medicine:

Do not use this medicine: Do not use this medicine if you are sensitive to any of the ingredients of this medicine

Before treatment with this medicine consult a doctor if

You are pregnant or breastfeeding

- You are suffering or have suffered in the past from impaired function of the digestive system (e.g. ulcer), or from problems in liver or kidney.
- If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.
- If you suffer from persistent or chronic cough such as smoker's cough, asthma, chronic bronchitis, emphysema, or coughs accompanied by surplus of mucus, you should consult your doctor before taking this medicine.

Special warnings regarding use of the medicine:

- · Do not use the medicine frequently or for a long period without consulting the doctor
- · This medicine contains methylparaben and propylparaben (preservatives), which may cause allergic reactions.

If you are taking or if you have recently taken other medicines including non prescription medicines, and food supplements, inform the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking a medicine or if you have just finished treatment with antibiotics as:

- · Ampicillin
- Amoxicillin
- Erythromycin Oxytetracycline

Pregnancy and breast-feeding:

If you are pregnant or breastfeeding, consult your doctor before starting use of this medicine.

Use in children:

This medicine is not recommended to children and infants below 2 years of age without a doctor recommendation.

3. How should you use this medicine?

If you are uncertain as to how to use this medicine, consult your doctor or your pharmacist.

The usual dosage, unless otherwise instructed by the doctor:

By Inhalation:

4ml, twice daily Adults Children over 12 years 2 ml, twice daily Children 6-12 years 1ml, twice daily Children 2-6 years 13 drops, twice daily

Adults and children over 12 years 4 ml, 3 times daily Children 6-12 years 2ml. 3 times daily

Children 2-6 years 20 drops, 3 times daily Take this medicine with or after a meal.

Directions for use:

Oral: Take the medicine with a large amount of water.

By Inhalation: Use a conventional inhaler.

Take care to measure the dose using the measuring cup or the bottle dropper.

Do not exceed the recommended dosage.

If there is no improvement in your condition within 7 days, refer to your doctor. If you have accidentally taken an overdose, or if a child has

accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the medicine package with you. If you forget to take this medicine at the required time, do not take a double dose. Take your next dose at the regular time and consult a doctor.

How can you contribute to the success of the treatment?

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

Side effects: As with any medicine, use of Mucoless Solution may cause side effects, in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue treatment and refer to a doctor immediately if: Allergic reactions are developed including rash, itching rash of the skin, bronchospasm, allergic reaction accompanied by swelling of the face, mouth, lips, tongue and / or throat that may cause difficulty breathing or swallowing (angioedema), anaphylaxis (severe allergic reaction).

new lesions appear in skin or mucous membranes, or the appearance

of peeling skin, severe blisters, with bleeding in the lips, eyes, mouth, nose or genitals.

- Other side effects Side effects which are not frequent (affect less than 1 out of
- 100 patients) - Nausea
- Vomiting - Discomfort in the stomach and intestine
- Diarrhea Rare side effects (affecting less than 1 in 1000 patients)
- Allergic reactions
- Skin rash
- Hypersensitivity Side effects that occur in an unknown number of patients
- Digestive Disorders
- Headache
- Dizziness
- Bronchospasm
- Anaphylactic chock
- Increase in liver enzymes (in researches)
- Sweating
- Chest tightness

If one of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

5. How should the medicine be stored?

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor! Do not use this medicine after the expiry date stated on the label/carton/

bottle. The expiry date refers to the last day of that month.

Store in a dark and dry place, below 25°C

Can be used for up to 4 months from first opening the bottle and not later than the expiry date that appears on the package.

6. Further information:

In addition to the active ingredient this medicine also contains: Methylparaben, Propylparaben, Purified water

What does the medicine look like and what is the content of the package:

Clear solution, colorless or yellowish, in a brown glass bottle with a dropper.

Manufacturer and registration holder: Vitamed pharmaceutical Industries Ltd.

P.O.B 114, Binyamina 3055002, Israel

This leaflet was checked and approved by the ministry of health in August 2014

Drug registration number: 1351131423