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

Ages 2-6 years: The medicine is dispensed according to a doctor's prescription only.
From age 6: The medicine is dispensed without a doctor's prescription.

KUFFEX DM SYRUP

Guaifenesin 100 mg/5 ml,
Dextromethorphan HBr 10 mg/5 ml
For a list of additional ingredients in the medicine, see Section 6 – Additional Information.

Read this package insert carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions refer to the doctor of pharmacist.
The medicine is not intended for children and infants below 2 years of age. In children below the age of 6: the medicine requires a doctor's prescription. The medicine must be used correctly. Consult the pharmacist if you need further information. Contact the doctor if the signs of the disease (symptoms) worsen or do not improve after 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

An expectorant syrup for relief of cough.

Therapeutic group: Guaifenesin is an expectorant and dextromethorphan is a cough suppressant.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredients or to any of the other ingredients contained in the medicine.
- Do not use in infants below 2 years of age.
- You are taking a medicine from the MAO inhibitors group, such as antidepressants or medicines for the treatment of Parkinson's disease and for two weeks after completing treatment with medicines from this group.

Before treatment with Kuffex DM, tell the doctor if:
- You are suffering or have suffered in the past from impaired function of the respiratory system (e.g., asthma) or the liver.
- You are sensitive to any food or medicine.
- The cough is accompanied by fever, itching or headaches.
- You are suffering from a persistent or chronic cough, together with conditions such as: smoking, asthma, chronic bronchitis, emphysema or if the cough is accompanied by secretion of a lot of phlegm.

Special warnings regarding use of the medicine: Do not use this medicine frequently or for a prolonged period without consulting the doctor!

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. You must especially tell the doctor or pharmacist if you are taking: medicines that affect the central nervous system (e.g., sedatives, hypnotics, medicines for parkinsonism, epilepsy); cough and cold medicines; antiasthmatics; antidepressants (from the MAO inhibitors group): if you are taking medicines from this group, do not use Kuffex DM syrup. This syrup can be used two weeks after completing treatment with medicines from this group.

Use of the medicine and food:
It is advisable not to take the medicine immediately after a meal.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, consult the doctor or pharmacist before using medicines.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are not sure.
This medicine is not intended for children and infants below two years of age.
In children from 2-6 years of age, use of the medicine requires a doctor's prescription.
In children 6 years of age and above, the medicine is sold without a doctor's prescription and will be dispensed by a pharmacist only.

- **The recommended dosage is usually:**
  For adults and children 12 years of age and above: 2 teaspoons (10 ml) every 4 hours.
  For children from 6-12 years of age: one teaspoon (5 ml) every 4 hours.
  Do not take more than 6 doses in 24 hours.
  Do not exceed the recommended dose.
- It is advisable to take the preparation with a glass of water.
- How to use the medicine – general directions: Be sure to measure the dose in the measuring cup enclosed in the package.
  1 teaspoon (5 ml) = 1 TSP
- If there is no improvement in your condition within 7 days, refer to the doctor.

If you accidentally took an overdose or if a child accidentally swallowed the medicine, contact the doctor immediately or proceed to a hospital emergency room and bring the package of the medicine with you.
- 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 Kuffex DM may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Refer to the doctor if the following side effects persist or are especially bothersome:
- Gastrointestinal discomfort, mild drowsiness. These effects generally pass within a short time following a period of adjustment to the medicine.

If any of the side effects gets worse, or if you have side effects not mentioned in the leaflet, consult the doctor.

Reporting side effects:
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
In addition, you can report to Perrigo via the following address:
www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the bottle and the package. The expiry date refers to the last day of that month.
- Store below 25°C. Do not refrigerate. After first opening the bottle the medicine can be used for 3 months.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:
Citric acid, FD&C red 40, glycerin, high fructose corn syrup, propylene glycol, natural cherry type flavour, menthol, sucralose, sodium citrate, sodium benzoate, purified water.
The amount of sodium per teaspoon (5 ml): 3 mg
The amount of preservative per teaspoon (5 ml): sodium benzoate 5 mg.
The amount of high fructose corn syrup per teaspoon (5 ml): 3,800 mg.

How does the medicine look and what are the contents of the package?
A bottle containing 118 ml of clear, orange-red liquid with a mild cherry aroma.

Manufactured for and marketed by: Super-Pharm (ISRAEL) Ltd., P.O.B. 2171, Hertzlia 4672516.

Name of registration holder and address: Perrigo Israel Agencies Ltd., 29 Lehi Street, Bnei Brak 51200.

Name of manufacturer and address: Perrigo Company, Allegan, Michigan, USA.

The leaflet was checked and approved by the Ministry of Health in June 2012.

Registration Number of the medicine in the National Drug Registry of the Ministry of Health: 14829.33671