In this leaflet:

1. **What MUCOSOLVAN syrup 30 mg/5 ml is and what it is used for**
   MUCOSOLVAN syrup 30 mg/5 ml is an expectorant which is used to thin the mucus in acute and chronic bronchial and lung diseases where thick, tenacious mucus is a problem.

2. **Before you take MUCOSOLVAN syrup 30 mg/5 ml**
   Do not take MUCOSOLVAN syrup 30 mg/5 ml:
   - if you are hypersensitive (allergic) to the active substance (ambroxol hydrochloride) or to any of the other ingredients of MUCOSOLVAN syrup 30 mg/5 ml.

   **Special care must be taken with MUCOSOLVAN syrup 30 mg/5 ml in the following circumstances:**

   In a very small number of cases, there have been reports of severe skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN) occurring in temporal association with the use of expectorants such as ambroxol hydrochloride. Most of these cases were attributable to the underlying disease and/or to other medication being taken concomitantly. In addition, during the early phase of Stevens-Johnson syndrome or TEN, patients may initially experience non-specific influenza-like symptoms such as fever, joint pain, rhinitis, cough and sore throat. Because of these non-specific influenza-like initial symptoms, symptomatic treatment with cough and cold medications, which is inappropriate, may be started. If new skin or mucosal lesions appear, therefore, medical advice should be sought immediately and the use of ambroxol hydrochloride discontinued.

   **Patients with impaired kidney or liver function**
   If you have impaired kidney function or severe liver disease, you must not take MUCOSOLVAN cough syrup 30 mg/5 ml except on medical advice. With ambroxol, as with any medicine which is broken down in the liver and then eliminated via the kidneys, accumulation of the breakdown products which are formed in the liver can be expected to occur in patients with severely impaired kidney function.

   In some rare bronchial diseases which are associated with excessive accumulation of secretions (such as primary ciliary dyskinesia), MUCOSOLVAN syrup 30 mg/5 ml should only be used under medical supervision because of the risk that secretions may accumulate.

   **Use in children**
   MUCOSOLVAN syrup 30 mg/5 ml must not be used in children under 2 years of age except on medical advice.

   **Taking other medicines**
   Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

   **Ambroxol and cough suppressants**
   Simultaneous use of MUCOSOLVAN syrup 30 mg/5 ml and cough suppressants may lead to the development of a dangerous accumulation of secretions owing to reduction of the cough reflex and should be undertaken only after careful risk-benefit assessment.

   **Pregnancy and breast-feeding**

   **Pregnancy**
   Ambroxol has been shown to pass into breast milk in animal studies. Use while breast-feeding is not recommended.
Driving and using machines
There is no evidence of any effect on the ability to drive or use machines. No relevant studies have been performed.

Important information about some of the ingredients of MUCOSOLVAN syrup 30 mg/5 ml
This medicine contains approximately 1.2 g sorbitol per 5 ml (equivalent to 4.9 g if the maximum recommended daily dose is taken). If you have been told that you have an intolerance to some sugars, please consult your doctor before taking MUCOSOLVAN syrup 30 mg/5 ml.

3. How to take MUCOSOLVAN syrup 30 mg/5 ml
Always take MUCOSOLVAN syrup 30 mg/5 ml exactly as described in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, the recommended doses are as follows:

**Children from 2 to 5 years of age:**
1.25 ml three times daily (equivalent to 22.5 mg ambroxol hydrochloride per day)

**Children from 6 to 12 years of age:**
2.5 ml two to three times daily (equivalent to 30 - 45 mg ambroxol hydrochloride per day)

**Adults and adolescents over 12 years of age:**
The usual dosage is 5 ml three times daily (equivalent to 90 mg ambroxol hydrochloride per day) for the first 2 - 3 days and 5 ml twice daily (equivalent to 60 mg ambroxol hydrochloride per day) thereafter.

For adults and adolescents over 12 years of age, the therapeutic effect may be enhanced by increasing the dosage to 10 ml twice daily (equivalent to 120 mg ambroxol hydrochloride per day).

Route and method of administration and duration of treatment
MUCOSOLVAN syrup 30 mg/5 ml is for oral use.

MUCOSOLVAN syrup 30 mg/5 ml can be taken with or without food and is dispensed with the aid of the measuring cup provided.

Please clean the measuring cup after each use by rinsing with warm water.

You should contact a doctor if your symptoms worsen or do not improve after 4 - 5 days.

If you feel that the effect of MUCOSOLVAN syrup 30 mg/5 ml is too strong or too weak, talk to your doctor or pharmacist.

If you take more MUCOSOLVAN syrup 30 mg/5 ml than you should
No specific symptoms of overdose have been reported to date. The symptoms observed in cases of accidental overdose or medication error are consistent with the side effects which may occur at recommended doses (see section 4). In case of overdose, please consult a doctor as symptomatic treatment may be required.
**Action to be taken in the event of side effects**

At the first signs of a hypersensitivity reaction, stop taking MUCOSOLVAN syrup 30 mg/5 ml.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. How to store MUCOSOLVAN syrup 30 mg/5 ml**

Keep out of the reach and sight of children.

Do not use MUCOSOLVAN syrup 30 mg/5 ml after the expiry date which is stated on the carton and the label.

**Storage conditions**

Do not store above 25°C

**Shelf life after first opening the bottle**

Use MUCOSOLVAN syrup 30 mg/5 ml within 6 months of first opening the bottle.

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

**6. Further information**

**What MUCOSOLVAN syrup 30 mg/5 ml contains:**

The active substance is ambroxol hydrochloride.

5 ml of the syrup contains 30 mg ambroxol hydrochloride.

The other ingredients are:

- Benzoic acid, liquid sorbitol (non-crystallising), hydroxyethylcellulose, glycerol 85%, acesulfame potassium, flavouring agents, purified water

**Notes:**

MUCOSOLVAN syrup 30 mg/5 ml is suitable for diabetics; 5 ml contains 1.2 g of carbohydrates. MUCOSOLVAN syrup 30 mg/5 ml does not contain alcohol.

**What MUCOSOLVAN syrup 30 mg/5 ml looks like and contents of the pack:**

MUCOSOLVAN syrup 30 mg/5 ml is a colourless liquid with a fruity odour.

MUCOSOLVAN syrup 30 mg/5 ml is available in original packs containing 100 ml and 250 ml.

Not all pack sizes may be marketed

**Marketing Authorisation Holder**

Boehringer Ingelheim International GmbH
Binger Straße 173
55216 Ingelheim am Rhein, Germany

**Manufacturer**

Delpharm Reims
10, Rue Colonel Charbonneaux
51100 Reims
France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Boehringer Ingelheim
Middle East & North Africa (Scientific Office) FZ-LLC
P.O. Box 505123
Dubai Healthcare City
Dubai, UAE.
Tel: +971 (4) 423 0400
Fax: +971 (4) 423 3637

**To report any side effect(s):**

- **Saudi Arabia:**
  - National Pharmacovigilance Center (NPC)
  - Fax: +966-11-205-7662
  - Toll-free: 8002490000
  - E-mail: npc.drug@sfd.gov.sa
  - Website: www.sfda.gov.sa/npc
- **Other countries:**
  - Please contact the relevant competent authority.

This leaflet was last revised in March 2013

**This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists