AMBROXOL EG LABO Conseil® 30 mg
Scored tablet
Ambroxol Hydrochloride

Read this carefully before you start taking Ambroxol as it contains important information for you. You should always take this medicine meticulously following the information given in this pamphlet and in consultation with your doctor:
- Keep this information pamphlet, might need to read it again.
- Ask your doctor for any advice or information.
- If you have any undesirable side effects, speak with your doctor. This also applies to any undesirable side effect that is not described in this pamphlet. See section 4.
- Talk to your doctor if your condition worsens, or if you do not feel any improvement after 8 to 10 days. Keep this medicine out of reach of children.

What does this information contain?
1. What is an AMBROXOL EG LABO 30 mg tablet and when is it used.
2. What you need to know before taking AMBROXOL EG LABO 30 mg, scored tablet.
3. How to take AMBROXOL EG LABO 30 mg, scored tablet.
4. What are the possible side effects.
5. How to store AMBROXOL EG LABO 30 mg, scored tablets.
6. Contents of the box and additional information.

1. WHAT IS AN AMBROXOL 30 mg scored tablet AND WHAT IT IS USED TO TREAT:
Pharmacotherapeutic group: Mucolytics, Anatomical Therapeutic Chemical code: R05CB06.
Treatment of bronchial secretion disorders in adults, particularly during acute bronchial infections and acute episodes of chronic bronchopneumopathies. This medicine is an expectorant, it facilitates the evacuation by cough of bronchial secretions.

2. WHAT INFORMATION SHOULD I KNOW BEFORE TAKING AMBROXOL EG LABO 30 mg scored tablet:
Do not take AMBROXOL EG LABO 30 mg, scored tablet:
- If you are allergic to any of the ingredients of this medicine, listed in section 6.
ALWAYS ADVISE YOUR DOCTOR BEFORE TAKING ANY MEDICATION.

Warnings and Precautions
Ask your doctor before taking AMBROXOL.
Serious skin reactions have been reported from taking ambroxol. If a rash appears on your skin (including mucosal lesions, for example in the mouth, throat, nose, eyes, genitals), stop using AMBROXOL EG LABO and contact your doctor immediately.
This medicine contains Lactose. Its use is not recommended for patients suffering from lactose intolerance (rare hereditary disease).
It is not advisable to take a cough suppressant medication or drugs that dry up the bronchial secretions during treatment with this medication.
ALWAYS ADVISE YOUR DOCTOR BEFORE TAKING ANY MEDICATION.

Other medicines and AMBROXOL EG LABO 30 mg, scored tablet
Always inform your doctor if you are taking or have recently taken or might take any other drugs in combination with this medication.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, if you believe you are pregnant or plan a pregnancy, ask your doctor before taking this medication.
It is not recommended to use this medicine during pregnancy or while breastfeeding.
If you discover that you are pregnant during treatment, consult with your doctor as whether to continue this treatment.
AMBROXOL EG LABO 30 mg, scored tablet contains lactose.
If your doctor advised you of any intolerance to certain sugars, contact your doctor before taking this medication.

3. HOW TO USE AMBROXOL EG LABO 30 mg, scored tablet:
Always follow the instructions given by your doctor while taking this medication.

Dosage
The recommended dosage of this medication is 1 to 2 tablets in the morning and in the evening.

Administration mode
Oral

Frequency of administration
Regular intervals

Duration of treatment
The duration of treatment should not exceed 8 to 10 days without medical advice.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS:
Like all drugs, this medication can cause side effects, however, they do not occur to everyone.
Rare: May occur at most in 1 in 1,000 people:
- Hypersensitivity reactions.
- Allergic reactions such as a rash, or hives on the skin.
- Rarely headache or Vertigo.

Unknown Frequency. Cannot be estimated from the available data:
- Anaphylactic reactions, including anaphylactic shock, angioedema (rapid swelling of the skin, subcutaneous tissue, mucous membrane or submucosal tissue), and pruritus.
- Severe skin reactions (including erythema multiforme, Stevens-Johnson syndrome / Lyell’s syndrome and generalized acute exanthematous pustulosis).

Also reported:
- Minor gastrointestinal side effects such as nausea, vomiting, heartburn and digestive upset have been reported infrequently. To limit the development of these side effects, this medicine should be taken with food.
- Occasional headache or vertigo in extremely rare cases.

Experience of side effects:
If you experience any serious side effects, including any not discussed in this pamphlet, speak with your doctor immediately. You can also report side effects to the French national reporting system: National Agency for the Safety of Medicines and Health Products (ANSM):
www.ansm.sante.fr
By reporting side effects, you are helping to provide more information on the safety of a medication.

5. HOW TO STORE AMBROXOL EG LABO 30 mg, scored tablet:
Keep this medicine out of reach of children.
Do not use this medication after the expiry date which is listed on the box. The expiry date refers to the last day of that month. There are no special storage conditions. Do not dispose of any medication in the sewage system or in the household garbage. Ask your pharmacist to eliminate medications that you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE BOX AND OTHER INFORMATION:
What AMBROXOL EG LABO 30 mg, scored tablet contains:
- The active substance is:
  Ambroxol hydrochloride .......................................................... 30 mg
- The other components are: Lactose monohydrate, microcrystalline cellulose, povidone K30, sodium carboxymethyl starch (type A), magnesium stearate.

What are the contents of the AMBROXOL EG LABO 30 mg, scored tablet box:
This medication is in the form of scored tablets. Box of 30.

Marketing Authorization Holder:
EG LABO – Laboratoires EuroGenerics
“Le Quintet” – Bâtiment A
12 rue Danjou
92517 BOULOGNE BILLANCOURT Cedex
FRANCE

Manufacturer
EGIS PHARMACEUTICALS PL S or EGIS PHARMACEUTICALS PL S
Bokényfalú ut 118-120
1166 BUDAPEST
HUNGARY

The last revision of this pamphlet by EG LABO was May 2016.
Detailed information about this medication is available on the ANSM (France) website: www.ansm.sante.fr