PACKAGE LEAFLET: INFORMATION FOR THE USER
Abrolen 30mg/5ml syrup
Ambroxol Hydrochloride

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. WHAT ABROLEN IS AND WHAT IT IS USED FOR

Abrolen has mucokinetic (stimulates the function of the fimbriated epithelium acting as expectorant) and mucolytic properties. It facilitates the removal of secretion of tracheobronchial tree, reducing by this way the stasis of mucus, with result the improvement of respiration (breathing).
As an auxiliary for the liquefaction of the mucus secretions of the respiratory tacts, in case of acute and chronic brochoalveotic disorders (bronchitis, emphysema, tracheobronchitis, chronic asthmatic bronchitis).
Also it is indicated for the anticipation of respiratory complications after surgical operations in the upper abdomen. It must be administered concomitantly with the proper antibiotic during acute bronchitis exacerbations.

2. BEFORE YOU TAKE ABROLEN

Do not use Abrolen
- if you are hypersensitive to the active substance or to any of the ingredients.
- if you take anticoughs or drugs processing atropinic action.

Take special care with Abrolen
Abrolen should be cautiously administered in patients with impaired bronchial motor function (at the rare malignant immotile cilia syndrome), due to a risk of secretion retention.

Using other medicines
Abrolen combination with other antitussive drugs might lead to dangerous bronchial-secretion retention, due to cough-reflex suppression. The indications for administration of a combined treatment should be cautiously evaluated.
Upon concomitant administration with Abrolen, the antibiotics amoxicillin, cefuroxime, ampicillin, doxycyclin and erythromycin penetrate into bronchial secretion at a greater extent.
There are no data about Abrolen interaction with other drugs used for treatment of bronchitis syndrome.

Taking Abrolen with food and drink
The drug must be taken before the meals.

Pregnancy and breast-feeding
Abrolen should not be taken during pregnancy, especially in the first trimester. Abrolen passes into mother milk, therefore it must not be administered during breast-feeding.

Driving and using machines
There are no data that Abrolen affects the ability to drive and operate machines.

Important information about some of the ingredients of Abrolen
Abrolen contains sorbitol solution, which is inappropriate at congenital fructose intolerance, since it might cause gastric irritation and diarrhoea.

Abrolen contains glycerol, which may cause headache, gastric irritation, and diarrhoea.

3. HOW TO USE ABROLEN

- Adults and children over 12 years old (60-120 mg daily in two equally divided doses):

1-2 measuring spoons twice daily.
The above dose regimen is indicated in acute disorders of the respiratory system and for the beginning of a treatment for acute chronic situations, which can be continued until 10 days.
In case that there is indication of treatment extension, the dose can be reduced to the half.

- Children 5-12 years old: 1/2 measuring spoon 2-3 times a day
- Children 2-5 years old: 1/4 measuring spoon 3 times a day

Abrolen is contraindicated in children less than 2 years of age

If you use more Abrolen than you should
Nausea, vomiting, flush throat, and gastric or abdominal pain are observed upon Abrolen overdosing. More rarely, blood pressure fall might occur.
Induced vomiting and fluid intake (tea, milk) are first measures for treatment of the intoxication. Gastric lavage is appropriate if Abrolen has been taken less than 1-2 hours ago.
The patient should be placed under monitoring.
Abrolen is not well eliminated by forced diuresis and haemodialysis.

4. POSSIBLE SIDE EFFECTS

Rarely, adverse gastrointestinal effects (nausea and abdominal pain) and allergic reactions (skin rash, facial swelling, severe respiration-impairment, temperature increase with fever) might be observed during Abrolen treatment.
Laxative effect is possible, due to the sorbitol and glycerol content as ingredients.

5. HOW TO STORE ABROLEN

Keep out of the reach and sight of children.
Store below 25^0C.
Do not use Abrolen after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Do not use Abrolen if you notice visible changes in the appearance of the medicinal product.
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.

6. FURTHER INFORMATION

What Abrolen contains
- The active substance is ambroxol hydrochloride.
- The other ingredients are hydroxyethyl cellulose, sorbitol solution, glycerol, benzoic acid, raspberry flavour, propylene glycol, tartaric acid, water purified.

What Abrolen looks like and contents of the pack
Abrolen syrup 30 mg/5 ml is a slightly viscous, clear and colourless syrup with odor of raspberry.
Contents of container: Abrolen syrup 30 mg/5 ml, 125 ml is in an amber coloured glass bottle.

Marketing Authorisation Holder
ALET Pharmaceuticals S.A.
26, Aidiniou str.
Haidari 124 61
Athens-Greece

Manufacturer
Specifar S.A.
1, 28 Octovriou str.
Ag. Varvara 123 51
Athens-Greece

The text was revised on 16.06.2009