Package leaflet: Information for the user

Ambroxol Sandoz 30 mg tablets
Ambroxol Sandoz 15 mg/5 mLmL
syrup
Ambroxol hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet

1. What Ambroxol Sandoz is and what it is used for

Ambroxol is an active N-demethylated metabolite of bromhexine possessing secretolytic and secretomotoric effects. Ambroxol thins mucus, making it easier to cough it out.
Ambroxol Sandoz is used as a phlegm loosening agent in case of productive cough accompanying lung and bronchial illnesses.

2. What you need to know before you use Ambroxol

Sandoz

Do not use Ambroxol Sandoz:
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6);

Warnings and precautions
- if you have a bronchial motor activity disorder along with a large production of secretion (risk of a mucous plug);
- if you have impaired renal function;
- if you have a severe liver disease;
- if you have a predilection for the development of peptic ulcers;
- usage in children under 2 years of age (use Ambroxol Sandoz 15 mg/5 mLmL syrup or use under a doctor's supervision)
- due to large content of the active substance, Ambroxol Sandoz 30 mg tablets should not be given to children under 6 years of age
- severe skin reactions have been reported in connection with the administration of ambroxol. If you get a rash (including lesions on the mucous membranes of the mouth, throat, nose, eyes, and reproductive organs), stop using Ambroxol Sandoz and immediately talk to your doctor.

Other medicines and Ambroxol Sandoz

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
No data about clinically significant adverse interactions with other medicines are available.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Ambroxol hydrochloride can cross the placental barrier. Usual precautions should be taken when using the medicine during pregnancy. Above all, using this medicine is not recommended during the first trimester.

Breast-feeding
Ambroxol hydrochloride is secreted into breast milk. Even though no adverse effects on the breast-fed baby are expected, breast-feeding mothers are not advised to use ambroxol.

Fertility
Ambroxol hydrochloride has no direct or indirect adverse effect on fertility.

Ambroxol Sandoz 30 mg tablets contain lactose as an excipient and the syrup contains sorbitol and sodium disulfite as excipients.
If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking this medicine.
Ambroxol Sandoz 15 mg/5 mLmL syrup contains sodium disulfite as an excipient that can, in rare cases, cause severe hypersensitivity reactions and bronchospasm.

3. How to use Ambroxol Sandoz

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Unless prescribed otherwise by your doctor, the following dosages are recommended:

Ambroxol Sandoz 30 mg tablets
Adults and children over 12 years of age
For the first 2–3 days, take 1 tablet 3 times per day (90 mg per day); after that, 1 tablet twice per day (60 mg per day).

Children aged 6–12 years
½ tablet 2–3 times per day (30–45 mg per day)

Ambroxol Sandoz 15 mg / 5 mL syrup
Adults and children over 12 years of age
For the first 2–3 days, take 2 measuring spoons (10 mL) of oral solution 2–3 times per day (60–90 mg per day); after that, 2 measuring spoons (10 mL) of oral solution twice per day (60 mg per day).

Children aged 6–12 years
One measuring spoon (5 mL) of oral solution 2–3 times per day (30–45 mg per day).

Children aged 2–5 years
½ measuring spoons (2.5 mL) of oral solution 3 times per day (22.5 mg per day).

Children under 2 years of age
½ measuring spoons (2.5 mL) of oral solution twice per day (15 mg).

Advice for diabetics
Ambroxol Sandoz 30 mg tablets
One tablet contains less than 0.01 bread units of carbohydrates.

Ambroxol Sandoz 15 mg / 5 mL syrup
One measuring spoon (corresponds to 5 mL of oral solution) contains 1.75 g of sorbitol, corresponding to 0.15 bread units of carbohydrates.

Method and duration of administration
Ambroxol Sandoz 30 mg tablets
The tablets should be taken after a meal, without chewing and with plenty of fluids (e.g. water, tea, or juice).

Ambroxol Sandoz 15 mg / 5 mL syrup
The oral solution (syrup) is taken after a meal by using the measuring spoon.

The package contains a measuring spoon bearing markings for 2.5 and 1.25 mL.

The duration of administration is determined on an individual basis, based on the indication

and the progress of the illness. Ambroxol should not be taken for longer than 4–5 days

without talking to a doctor.

Note
Ingestion of fluids improves the secretolytic effect of ambroxol.

If you feel that the effect of Ambroxol Sandoz is too strong or too weak, talk to your doctor or pharmacist.

If you use more Ambroxol Sandoz than you should
No specific symptoms of overdose have currently been reported in humans.
Accidental overdose and/or misuse of the medicine can cause side effects listed in section 4.
If overdose symptoms occur, talk to a doctor.

If you forget to use Ambroxol Sandoz
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Patients using Ambroxol Sandoz have reported the following side effects:

Common (can occur in up to 1 person in 10)
- Changes in sense of taste
- Numbness in throat
- Nausea, numbness in the mouth

Uncommon (can occur in up to 1 person in 100)
- Vomiting, diarrhoea, indigestion, stomach pain, dry mouth

Rare (can occur in up to 1 person in 1,000)
- Hypersensitivity reactions
- Rash, hives

Unknown (incidence cannot be estimated from available data)
- Anaphylactic reactions, incl. anaphylactic shock, angioedema (sudden swelling of the

skin, subcutaneous, mucosal, or submucosal tissues) and itching

- Severe skin reactions (incl. erythema multiforme, Stevens-Johnson syndrome / toxic epidermal necrolysis, and acute generalised exanthematous pustulosis)
- Dry throat

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ambroxol Sandoz

Ambroxol Sandoz 30 mg tablets:
This medicine does not require any special storage conditions.

Ambroxol Sandoz 15 mg / 5 mL syrup:
This medicine does not require any special storage conditions. After initial opening, use the medicine within 12 months.

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and

other information What

Ambroxol contains
- The active substance is ambroxol.
  Ambroxol Sandoz 30 mg tablets
  Each tablet contains 30 mg of ambroxol hydrochloride.

  Ambroxol Sandoz 15 mg / 5 mL
  1 mL of syrup contains 3 mg of ambroxol hydrochloride.

- Other excipients:
  Ambroxol Sandoz 30 mg tablets
  Calcium hydrophosphate, lactose monohydrate, magnesium stearate, corn starch, poly(P-carboxymethyl) sodium starch, silica

  Ambroxol Sandoz 15 mg / 5 mL syrup
  Benzoic acid, citric acid, glycerol, sodium cyclamate, sodium hydroxide, sodium disulfite, polyvidone, sorbitol, distilled water, aroma agents

What Ambroxol Sandoz looks like and contents of the pack
Ambroxol Sandoz 30 mg
Ambroxol Sandoz 30 mg is a flat white round tablet with a bevelled edge and a score on one side. One original package contains 20 tablets.

Ambroxol Sandoz 15 mg / 5 mL
Ambroxol Sandoz 15 mg / 5 mL syrup is a clear or nearly clear colourless to light yellow liquid. One original package contains 100 mL or 250 mL of syrup.
The package contains a measuring spoon bearing markings

for 2.5 and 1.25 mL. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Sandoz d.d.
Verovškova 57
1000 Ljubljana,
Slovenia

Manufacturers:

Ambroxol Sandoz 30 mg tablets:

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
D-39179 Barleben,
Germany

LEK S. A.,
Ul. Podlipie 16
95-010
Strykow,
Poland

Ambroxol Sandoz 15 mg / 5 mL syrup:

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
D-39179 Barleben,
Germany

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

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