PACKAGE LEAFLET: INFORMATION FOR THE USER

Ambrobene Extra Strength 6 mg/ml Oral Solution
Ambroxol hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 (within 3 days in children aged less than 6 years).

What is in this leaflet:

1. What Ambrobene Extra Strength 6 mg/ml Oral Solution is and what it is used for
2. What you need to know before you take Ambrobene Extra Strength 6 mg/ml Oral Solution
3. How to take Ambrobene Extra Strength 6 mg/ml Oral Solution
4. Possible side effects
5. How to store Ambrobene Extra Strength 6 mg/ml Oral Solution
6. Contents of the pack and other information

1. What Ambrobene Extra Strength 6 mg/ml Oral Solution is and what it is used for

Ambrobene Extra Strength 6 mg/ml Oral Solution contains the active ingredient ambroxol hydrochloride. This belongs to a group of medicines called mucolytics that help clear airways from mucus.

Ambrobene Extra Strength 6 mg/ml Oral Solution is used to treat airway conditions that require the elimination of mucus (phlegm) in adults and children older than 2 years of age. It works by making mucus thinner so that it can be cleared more easily.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days (within 3 days in children aged less than 6 years).

2. What you need to know before you take Ambrobene Extra Strength 6 mg/ml Oral Solution

Do NOT take Ambrobene Extra Strength 6 mg/ml Oral Solution:
- If you are allergic to ambroxol hydrochloride or any other ingredients of this medicine (listed in section 6).
- Children up to 2 years.
- If you have rare hereditary problems of fructose intolerance.

Warnings and precautions
Talk to your doctor or pharmacist before taking Ambrobene Extra Strength 6 mg/ml Oral Solution:
- if you have had a cough for a long time
- if you have asthma or suffer from serious asthma attacks
- if you have or have had liver or kidneys problems
- if you have peptic or duodenal ulcers
- if you have a condition called primary ciliary dyskinesia with compromised airways movement.

There have been reports of severe skin reactions associated with the administration of ambroxol hydrochloride. If you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop using Ambrobene Extra Strength 6 mg/ml Oral Solution and contact your doctor immediately.

Children
Ambrobene Extra Strength 6 mg/ml Oral Solution is contraindicated in children up to 2 years of age.

Other medicines and Ambrobene Extra Strength 6 mg/ml Oral Solution
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Ambrobene Extra Strength 6 mg/ml Oral Solution should not be taken with medicines that inhibit cough e.g. with codeine or dextrometorphan.

Taking Ambrobene Extra Strength 6 mg/ml Oral Solution with antiobiotics (medicines used to treat infections) e.g. amoxicillin, cefuroxim, erythromycin, leads to increase of antibiotics concentrations in mucus.

Taking Ambrobene Extra Strength 6 mg/ml Oral Solution with food and drink
Ambrobene Extra Strength 6 mg/ml Oral Solution should be taken after meals.

Pregnancy and breast-feeding
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.

No harmful effects have been observed during pregnancy. However, its use is not recommended in pregnancy especially during the first 3 months of pregnancy.

It is not recommended to use Ambrobene Extra Strength 6 mg/ml Oral Solution if you are breast-feeding, however, you should not expect any adverse effects on breast-fed children.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed with ambroxol hydrochloride.
There is no evidence that Ambrobene Extra Strength 6 mg/ml Oral Solution would influence your ability to drive and use machines.

Ambrobene Extra Strength 6 mg/ml Oral Solution contains sorbitol
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Ambrobene Extra Strength 6 mg/ml Oral Solution

Always take Ambrobene Extra Strength 6 mg/ml Oral Solution 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 otherwise prescribed, the following doses are recommended for Ambrobene Extra Strength 6 mg/ml Oral Solution (5 ml dose = one syringe):

Adults and children over 12 years:
During the first 2 to 3 days 5 ml (one syringe) of Ambrobene Extra Strength 6 mg/ml Oral Solution should be taken, 3 times daily (every 8 hours), corresponding to 90 mg of ambroxol hydrochloride per day.

After that, take 5 ml (one syringe) of Ambrobene Extra Strength 6 mg/ml Oral Solution twice a day (every 12 hours), equivalent to 60 mg ambroxol hydrochloride per day.

An increased effectivness is possible with the dosage of 10 ml of 6 mg/ml solution two times a day (every 12 hours) (corresponding to 120 mg of ambroxol hydrochloride per day).

Use in children
Children under 2 years:

This medicine is contraindicated in children under 2 years.

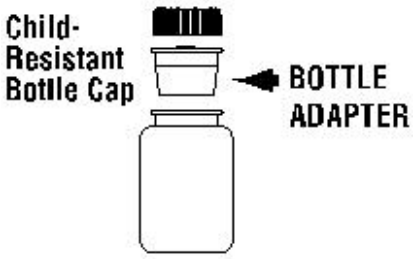
Children 2 to 5 years:
Take 1.25 ml (a quarter of a syringe) of Ambrobene Extra Strength 6 mg/ml Oral Solution 3 times a day (every 8 hours), corresponding to 22.5 mg of ambroxol hydrochloride per day.

Children 6 to 12 years:
Take 2.5 ml (half a syringe) of Ambrobene Extra Strength 6 mg/ml Oral Solution 2 to 3 times a day (every 12 or 8 hours), corresponding to 30-45 mg of ambroxol hydrochloride per day.

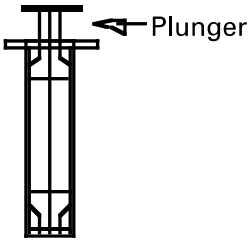
How to take
This medicine is for oral use only.
Ambrobene Extra Strength 6 mg/ml Oral Solution should be taken after meals, with the help of the attached dosing device (oral syringe).
It is recommended to drink a glass of water after administration and plenty of liquid during the day.

Consult your doctor if your symptoms do not improve or even deteriorate after 5 days (within 3 days in children aged less than 6 years).

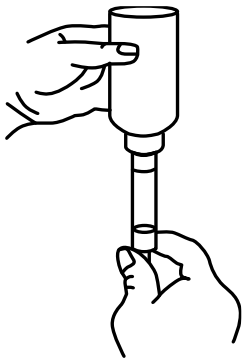
Please follow the instructions carefully to ensure proper dosing of the oral solution.



ORAL DISPENSER



1. Shake closed bottle before each use
2. Remove child-resistant bottle cap
3. Make sure the bottle adapter is pushed into the neck of the bottle
4. Before inserting the oral syringe into the bottle adapter, push the plunger completely down. Then insert the oral syringe firmly into the opening of the bottle adapter
5. Turn the entire unit (bottle and oral syringe) upside down
6. Pull out syringe plunger until the correct amount is withdrawn (see figure below)



7. Turn the entire unit the correct way up and remove the syringe from the adapter
8. Dispense directly into mouth. Do not mix with any liquid prior to dispensing
9. After you have swallowed the medicine drink some tea or juice to wash out and swallow remaining content in the mouth
10. Close the bottle with the child-resistant cap after each use
11. Disassemble the oral syringe, rinse under running tap water and air dry prior to next use.

If you take more Ambrobene Extra Strength 6 mg/ml Oral Solution than you should
If you take too much of this medicine, contact youe nearest hospital casuality department or your doctor immediately.
Please take this leaflet and any remaining solution with you to the hospital or doctor so they know what has been taken.

If you forget to take Ambrobene Extra Strength 6 mg/ml Oral Solution
If you forget to take a dose, take it as soon as your remember unless it is nearly time for your next dose. If this happens skip the missed dose and take the remaining dose as normal. 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 or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you experience any of the following side effects, **stop taking this medicine immediately and contact your doctor**:

Common side effects (may affect up to 1 in 10 people):
- change in the way things taste
- numbing of the throat
- diarrhoea, numbing of the mouth, feeling sick

Uncommon side effects (may affect up to 1 in 100 people):
- stomach pain, being sick, indigestion, dry mouth
- allergic reactions (including itchy skin or rashes, difficulty breathing, faster heart rate, swelling of the face or throat, swelling of skin)
- fever

Rare side effects (may affect up to 1 in 1,000 people):
- hearthburn, dry throat
- Hypersensitivity reactions
- Rash, urticaria

Very rare side effects (may affect up to 1 in 10,000 people):

- constipation, drooling
- difficult or painful urination
- runny nose, dryness of airways

Not known (frequency cannot be estimated from available data):
- Anaphylactic reactions including anaphylactic shock, angioedema (rapidly developing swelling of the skin, subcutaneous, mucosa or submucosal tissues) and pruritus
- Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis)..

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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ambrobene Extra Strength 6 mg/ml Oral Solution

Keep out of the sight and reach of children.

Do NOT use Ambrobene Extra Strength 6 mg/ml Oral Solution after the expiry date which is stated on the bottle label and carton after the abbreviation EXP. The expiry date refers to the last day of that month.

Do not store above 30˚C.

Store in the upright position.

Use Ambrobene Extra Strength 6 mg/ml Oral Solution oral solution within 6 months of first opening of the bottle.

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 to protect the environment.

6. Contents of the pack and other information

What Ambrobene Extra Strength 6 mg/ml Oral Solution contains

- The active substance is ambroxol hydrochloride. Each 1 ml of the oral solution contains 6 mg of ambroxol hydrochloride.
- The other ingredients are acesulfame potassium (E950), benzoic acid (E210), glycerol (E422), hydroxyethylcellulose (E1525), propylene glycol (E1520), sorbitol liquid (E420), raspberry flavour, vanilla flavour and water purified.

What Ambrobene Extra Strength 6 mg/ml Oral Solution looks like and contents of the pack

Ambrobene Extra Strength 6 mg/ml Oral Solution is a clear, colourless solution with raspberry odour.

Brown PET bottle with child-resistant PP closure with dosing crimp insert and oral syringe (5 ml syringe, graduated every 0.25 ml).

Pack size: 100 ml.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:
Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturers:
Merckle GmbH/Merckle, Blaubeuren
Ludwig-Merckle Strasse 3,
D-89143 Blaubeuren
Germany

TEVA PHARMA S.L.U.
C/C, n. 4, Poligono Industrial Malpica,
50016 Zaragoza
Spain

Teva Operations Sp. z.o.o
ul. Mogilska 80.
31-546, Krakow
Poland

Teva Czech Industries s.r.o.
Ostravska 29, c.p. 305,
4770 Opava-Komarov
Czech Republic

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	Ambrobene 6 mg/ml, perorální roztok
Germany	Ambro-ratiopharm 6 mg/ml Lösung zum Einnehmen
Hungary	Ambroxol Teva 6 mg/ml belsőleges oldat
Ireland	Ambrobene Extra Strength 6 mg/ml Oral Solution
Poland	Ambroxol Ratio123
Slovakia	Ambrobene 6 mg/ml
Spain	FormulaMucol 6 mg/ml solución oral EFG

This leaflet was last revised in July 2016.

Detailed information on this medicine is available on the website of www.hpra.ie.