Version 3.0, 04/2013

SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

/…/ 30 mg effervescent tablets
/…/ 60 mg effervescent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One effervescent tablet contains 30 mg of ambroxol hydrochloride.
One effervescent tablet contains 60 mg of ambroxol hydrochloride.

Excipients with known effect:
Each effervescent tablet contains 120 mg of anhydrous lactose, 5.5 mmol (127 mg) of sodium and 29 mg of sorbitol per tablet (see section 4.4).
Each effervescent tablet contains 110 mg of anhydrous lactose, 5.5 mmol (127 mg) of sodium and 29 mg of sorbitol per tablet (see section 4.4).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablet

/…/ 30 mg: White, round tablets, 18 mm in diameter, with a break mark on one side, engraved “3” on each tablet half and with a cherry odour. The tablet can be divided into equal doses.
/…/ 60 mg: White, round tablets, 18 mm in diameter, with a break mark on one side and a cherry odour. The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mucolytic therapy of productive cough in acute or chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.

/…/ 30 mg effervescent tablets are indicated in adults, adolescents and children over 6 years of age.
/…/ 60 mg effervescent tablets are indicated in adults and adolescents over 12 years of age.

4.2 Posology and method of administration

Posology

The following dosages are recommended for /…/:

<[/…/ 30 mg:]>
Adults and adolescents over 12 years of age
One /…/ 30 mg effervescent tablet 3 times daily (equivalent to 90 mg ambroxol hydrochloride per day) during the first 2 to 3 days. After that, one /…/ 30 mg effervescent tablet twice daily (equivalent to 60 mg ambroxol hydrochloride per day).

For adults, the dose may be increased up to 60 mg ambroxol hydrochloride twice daily (equivalent to 120 mg ambroxol hydrochloride per day) if needed.

Children from 6 to 12 years of age

Half /…/ 30 mg effervescent tablet (15 mg ambroxol hydrochloride) administered 2 to 3 times daily (equivalent to 30–45 mg ambroxol hydrochloride per day).

Children under 6 years of age
/…/ 30 mg effervescent tablets are contraindicated in children under 6 years of age (see section 4.3).

<[/…/ 60 mg:]>
Adults and adolescents over 12 years of age
Half /…/ 60 mg effervescent tablet 3 times daily (equivalent to 90 mg ambroxol hydrochloride per day) during the first 2 to 3 days. After that, half /…/ 60 mg effervescent tablet twice daily (equivalent to 60 mg ambroxol hydrochloride per day).

For adults, the dosage may be increased up to 60 mg ambroxol hydrochloride twice daily (equivalent to 120 mg ambroxol hydrochloride per day) if needed.

Children under 12 years of age
Due to the high content of the active substance, /…/ 60 mg effervescent tablets are contraindicated in children under 12 years of age (see section 4.3).
For administration in children under 12 years of age, other pharmaceutical strengths/forms may be available.

Patients with renal or hepatic impairment
There are no data available for use of ambroxol in patients with hepatic or renal impairment (see section 4.4).

Method of administration
/…/ effervescent tablets are for oral use.
/…/ effervescent tablets should not be taken longer than 4-5 days without the advice of a doctor. If symptoms don't improve or worsen in 5 days of treatment, medical advice should be sought.
The effervescent tablets should be dissolved in a glass of water and the solution consumed after meals.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

/…/ 30 mg effervescent tablets are contraindicated in children under 6 years of age.
Due to the high content of the active substance, /…/ 60 mg effervescent tablets are contraindicated in children under 12 years of age (see section 4.2).

4.4 Special warnings and precautions for use

There have been reports of severe skin reactions such as erythema multiforme, Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and acute generalised exanthematous pustulosis (AGEP) associated with the administration of ambroxol. If symptoms or signs of a progressive skin rash (sometimes associated with blisters or mucosal lesions) are present, ambroxol treatment should be discontinued immediately and medical advice should be sought.

In the presence of impaired renal function or severe hepatopathy, ambroxol may be used only after consulting a physician. As for any medication with hepatic metabolism followed by renal elimination, accumulation of the metabolites of ambroxol generated in the liver can be expected in the presence of severe renal insufficiency.

This medicinal product contains 116 mg of sorbitol and 480 mg of anhydrous lactose per maximum recommended daily dose of /…/ (29 mg sorbitol and 120 mg anhydrous lactose per tablet). This medicinal product contains 58 mg of sorbitol and 220 mg of anhydrous lactose per maximum

recommended daily dose of /…/ (29 mg sorbitol and 110 mg anhydrous lactose per tablet). Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine**.**

This medicinal product contains 5.5 mmol (127 mg) of sodium per /.../ effervescent tablet . To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant unfavourable interaction with other medications has been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy
Ambroxol hydrochloride crosses the placental barrier. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Extensive clinical experience after the 28th week of pregnancy has shown no evidence of harmful effects on the foetus. Nonetheless, the usual precautions regarding the use of drugs during pregnancy should be observed. Especially during the first trimester, the use of /…/ is not recommended.

Breast-feeding
Ambroxol hydrochloride is excreted in breast milk. Although unfavourable effects on breastfed infants would not be expected, /…/ is not recommended for use in nursing mothers.

Fertility
Animal studies do not indicate harmful effects of ambroxol with respect to fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

There is no evidence for an effect on the ability to drive and use machines.
Studies on the effects on the ability to drive and use machines have not been performed.

4.8 Undesirable effects

Frequency categories for adverse reactions are defined using the following convention:

Very common: (≥1/10)
Common: (≥1/100 to <1/10)
Uncommon: (≥1/1,000 to <1/100)
Rare: (≥1/10,000 to <1/1,000)
Very rare: (<1/10,000)
Not known: (cannot be estimated from the available data).

Immune system disorders:
Rare: Hypersensitivity reactions
Not known: Anaphylactic reactions including anaphylactic shock, angioedema and pruritus

Nervous system disorders:
Common: Dysgeusia (e.g. changed taste)

Respiratory, thoracic and mediastinal disorders:
Common: Pharyngeal hypoaesthesia

Gastrointestinal disorders:
Common: Nausea, oral hypoaesthesia
Uncommon: Vomiting, diarrhoea, dyspepsia, abdominal pain, dry mouth
Not known: Dry throat

Skin and subcutaneous tissue disorders:
Rare: Rash, urticaria
Not known: Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalized exanthematous pustulosis)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

No specific overdose symptoms have been reported in man to date. Based on accidental overdose and/or medication error reports the observed symptoms are consistent with the known side effects of ambroxol hydrochloride at recommended doses and may need symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mucolytics, ATC code: R05CB06

Ambroxol, a substituted benzylamine, is a metabolite of bromhexine. It differs from bromhexine by the absence of a methyl group and the introduction of a hydroxyl group in the *para-trans* position of the cyclohexyl ring. Although its mechanism of action has yet to be completely elucidated, secretolytic and secretomotor effects have been found in various investigations, however.

On average, action following oral administration commences after 30 minutes and persists for 6 – 12 hours depending on the extent of the single dose.

In preclinical investigations, it increases the proportion of serous bronchial secretion. The transport of mucus is thought to be promoted by the reduction of viscosity and the activation of the ciliated epithelium.

Ambroxol induces activation of the surfactant system by acting directly on the type 2 pneumocytes of the alveoles and the Clara cells in the region of the small airways.

It promotes the formation and outward transfer of surface-active material in the alveolar and bronchial region of the foetal and adult lungs. These effects have been demonstrated in cell cultures and *in vivo* on various species.

A beneficial effect on the frequency of exacerbations or lung function has not been unequivocally established in COPD patients.

Following use of ambroxol, concentrations of the antibiotics amoxicillin, cefuroxime, erythromycin and doxycycline in the sputum and in the bronchial secretion are increased. To date, it has not been possible to surmise a clinical relevance from this.

5.2 Pharmacokinetic properties

Absorption
Ambroxol is practically completely absorbed following oral administration. T_{max} following oral administration is 1 - 3 hours. The absolute bioavailability of ambroxol on oral administration is reduced by approx. one third by a first-pass effect.

Distribution
Binding to plasma proteins is approx. 85% (80 - 90%). Ambroxol crosses the placental barrier and passes into the cerebrospinal fluid and breast-milk.

Biotransformation
The hepatic biotransformation produces dibromoanthranilic acid and glucuronide conjugates.

Elimination
The terminal half-life in the plasma is 7 - 12 hours. The plasma half-life of the sum of ambroxol and its metabolites is approx. 22 hours.
Excretion is 90% renal in the form of metabolites formed in the liver. Unchanged ambroxol accounts for less than 10% of renal excretion.
Due to the high protein binding and the high volume of distribution, as well as the slow redistribution from the tissue to the blood, major elimination of ambroxol through dialysis or forced diuresis is not expected.
Clearance of ambroxol is diminished by 20 - 40% in severe hepatic diseases. In severe renal dysfunction, an accumulation of the metabolites of ambroxol must be expected.

5.3 Preclinical safety data

Ambroxol hydrochloride has a low index for acute toxicity. In repeat-dose studies, oral doses of 150 mg/kg/day (mouse, 4 weeks), 50 mg/kg/day (rat, 52 and 78 weeks), 40 mg/kg/day (rabbit, 26 weeks) and 10 mg/kg/day (dog, 52 weeks) were the no-observed adverse effect level (NOAEL). No toxicological target organs were detected. Four week intravenous toxicity studies with ambroxol hydrochloride in rats (4, 16 and 64 mg/kg/day) and in dogs (45, 90 and 120 mg/kg/day (infusion 3 h/day)) showed no severe local and systemic toxicity including histopathology. All adverse effects were reversible.

Ambroxol hydrochloride was neither embryotoxic nor teratogenic when tested at oral doses up to 3000 mg/kg/day in rats and up to 200 mg/kg/day in rabbits. The fertility of male and female rats was not affected up to 500 mg/kg/day. The NOAEL in the peri- and post-natal development study was 50 mg/kg/day. At 500 mg/kg/day, ambroxol hydrochloride was slightly toxic for dams and pups, as shown by a retarded body-weight development and reduced litter size.

Genotoxicity studies *in vitro* (Ames and chromosome aberration test) and *in vivo* (mouse micronucleus test) did not reveal any mutagenic potential of ambroxol hydrochloride.

Ambroxol hydrochloride did not show any tumorigenic potential in carcinogenicity studies in mice (50, 200 and 800 mg/kg/day) and rats (65, 250 and 1000 mg/kg/day) when treated with a dietary admixture for 105 and 116 weeks, respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, anhydrous
Sodium hydrogen carbonate
Sodium carbonate anhydrous

Saccharin sodium
Sodium cyclamate
Sodium chloride
Sodium citrate
Lactose, anhydrous
Mannitol
Sorbitol (E 420)
Simeticone
Cherry flavour:
Natural/nature identical flavouring substances
Maltodextrin
Mannitol (E421)
Gluconolactone (E575)
Sorbitol (E420)
Acacia (E414)
Silica, colloidal anhydrous (E551)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

/…/ are packed into polypropylene tubes which are closed with polyethylene desiccant stoppers. The stoppers are filled with Silica gel dessicant to protect the tablets against moisture.

Pack sizes: 10 and 20 effervescent tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

After dissolution of the /…/ effervescent tablet, the solution should be colourless, clear and without particles.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation: {DD month YYYY}>
<Date of latest renewal: {DD month YYYY}>

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

[To be completed nationally]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

/…/ 30 mg effervescent tablets
/…/ 60 mg effervescent tablets

ambroxol hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One effervescent tablet contains 30 mg ambroxol hydrochloride.
One effervescent tablet contains 60 mg ambroxol hydrochloride.

3. LIST OF EXCIPIENTS

Contains lactose, sorbitol (E420) and sodium (see leaflet for further information).

With cherry flavour

4. PHARMACEUTICAL FORM AND CONTENTS

Effervescent tablet

10 effervescent tablets
20 effervescent tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Dissolve the tablets in a glass of water and drink.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

<[/…/ 30 mg:]>
For wet (productive) cough in adults, adolescents and children over 6 years of age. Makes mucus thinner and loosens it, so that it can be coughed up more easily.

<u>Adults and adolescents over 12 years of age:</u>
First 2-3 days: One effervescent tablet (30 mg) three times a day.
After that, take one effervescent tablet (30 mg) twice a day.
If necessary, in adults, dose can be increased to 2 tablets (60 mg) twice a day.

<u>Children from 6 to 12 years of age:</u>
Half effervescent tablet (15 mg) two to three times a day.

/…/ 30 mg must not be used in children under 6 years of age.

<[/…/ 60 mg:]>
For wet (productive) cough in adults and adolescents over 12 years of age. Makes mucus thinner and loosens it, so that it can be coughed up more easily.

Adults and adolescents over 12 years of age:
First 2-3 days: Half effervescent tablet (30 mg) three times a day.
After that, take half effervescent tablet (30 mg) twice a day.
If necessary, in adults, dose can be increased to one tablet (60 mg) twice a day.

/…/ 60 mg must not be used in children under 12 years of age.

/…/ should not be taken longer than 4-5 days without the advice of a doctor. Consult your doctor if your symptoms do not improve or get worse after 5 days.

Do not use if you are allergic to ambroxol or any of the ingredients of this medicine.

<For wet cough
Over 6 years of age>

<For wet cough
Over 12 years of age>

16. INFORMATION IN BRAILLE

/…/ 30 mg
/…/ 60 mg

PARTICULARS TO APPEAR ON THE THE IMMEDIATE PACKAGING

Tube label

1. NAME OF THE MEDICINAL PRODUCT

/…/ 30 mg effervescent tablets
/…/ 60 mg effervescent tablets

ambroxol hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One tablet contains 30 mg ambroxol hydrochloride.
One tablet contains 60 mg ambroxol hydrochloride.

3. LIST OF EXCIPIENTS

Contains lactose, sorbitol (E420) and sodium.

4. PHARMACEUTICAL FORM AND CONTENTS

10 tablets
20 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Dissolve the tablets in a glass of water and drink.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
220 Hafnarfjordur
Iceland

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

<[/…/ 30 mg:]>
For wet (productive) cough in adults, adolescents and children over 6 years of age.

Adults and adolescents over 12 years of age:
First 2-3 days: One tablet three times a day.
After that, take one tablet twice a day.
If necessary, in adults, dose can be increased to 2 tablets twice a day.

Children from 6 to 12 years of age:
Half tablet two to three times a day.

/…/ 30 mg must not be used in children under 6 years of age.

<[/…/ 60 mg:]>
For wet (productive) cough in adults and adolescents over 12 years of age.

Adults and adolescents over 12 years of age:
First 2-3 days: Half tablet three times a day.
After that, take half tablet twice a day.
If necessary, in adults, dose can be increased to one tablet twice a day.

/…/ 60 mg must not be used in children under 12 years of age.

/…/ should not be taken longer than 4-5 days without the advice of a doctor. Consult your doctor if your symptoms do not improve or get worse after 5 days.

16. INFORMATION IN BRAILLE

PACKAGE LEAFLET

Package leaflet: Information for the user

/…/ 30 mg effervescent tablets
/.../ 60 mg effervescent tablets

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 /…/ is and what it is used for

/.../ contains the active ingredient ambroxol hydrochloride. This belongs to a group of medicines called mucolytics (cough and cold preparations) that help clear airways from mucus.

/.../ 30 mg effervescent tablets are used to treat wet (productive) cough in adults, adolescents and children over 6 years of age.
/.../ 60 mg effervescent tablets are used to treat wet (productive) cough in adults and adolescents over 12 years of age.

Wet (productive) cough is associated with disorders of the lungs and bronchial tubes when excess mucus is produced. /…/ works by making mucus thinner and loosens it, so that it can be coughed up more easily.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you take /…/

Do not use /…/
- if you are allergic to ambroxol or any of the other ingredients of this medicine (listed in section 6).
- in children under six years of age.
- in children under twelve years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking /.../:
- if you have or have had liver or kidney problems.

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

Children
/…/ 30 mg effervescent tablets must not be used in children under 6 years of age.
Due to the high content of the active substance, /…/ 60 mg effervescent tablets must not be used in children under 12 years of age.

Other medicines and /…/
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
There are no known interactions of /…/ with other medicines.

/…/ with food
/…/ can be used with food and should be taken after meals.

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.

Pregnany
Ambroxol crosses the placental barrier and reaches the unborn child. /…/ should not be used during pregnancy, especially during the first three months.

Breast-feeding
Ambroxol is excreted in breast milk. /…/ is not recommended for use in nursing mothers.

Driving and using machines
This medicine should not affect your ability to drive or use machines.

/…/ contains sorbitol (E420), lactose and sodium
If your doctor has told you have an intolerance to some sugars or if you are on a sodium constricted diet, contact your doctor before taking this medicine.
Each effervescent tablet contains 29 mg of sorbitol, 120110 mg of lactose (anhydrous) and 5.5 mmol (127 mg) of sodium.

3. How to take /…/

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed, the following doses are recommended for /.../:

<[/…/ 30 mg:]>
Adults and adolescents over 12 years of age
During the first 2 to 3 days, one 30 mg effervescent tablet should be taken three times daily (corresponding to 90 mg of ambroxol hydrochloride per day).

After that, take one 30 mg effervescent tablet twice a day (corresponding to 60 mg ambroxol hydrochloride per day).

If necessary, the dosage in adults may be increased to two 30 mg effervescent tablets (60 mg ambroxol hydrochloride) twice a day (corresponding to 120 mg of ambroxol hydrochloride per day).

Children from 6 to 12 years of age
½ (half) 30 mg effervescent tablet (15 mg ambroxol hydrochloride) two to three times a day (corresponding to 30–45 mg of ambroxol hydrochloride per day).

Children under 6 years of age
/…/ 30 mg effervescent tablets must not be used in children under 6 years of age.

<[/…/ 60 mg:]>
Adults and adolescents over 12 years of age
During the first 2 to 3 days, ½ (half) 60 mg effervescent tablet should be taken three times daily (corresponding to 90 mg of ambroxol hydrochloride per day).

After that, take ½ (half) 60 mg effervescent tablet twice a day (corresponding to 60 mg ambroxol hydrochloride per day).

If necessary, the dosage in adults may be increased to one 60 mg effervescent tablet twice a day (corresponding to 120 mg of ambroxol hydrochloride per day)

Children under 12 years of age
Due to the high content of the active substance, /…/ 60 mg effervescent tablets must not be used in children under 12 years of age. Other strengths or forms of this medicine may be available for children under 12 years of age; ask your doctor or pharmacist.

Patients with kidney or liver impairment
If you have kidney or severe liver impairment, you should not use /…/ unless prescribed by your doctor. Your dose or dosage interval might need to be adjusted.

How to take
This medicine is for oral use only.
Dissolve the effervescent tablets in a glass of water and drink.
Once the effervescent tablet has dissolved, the solution should be colourless, clear and without particles.
/.../ should be taken after meals. The effervescent tablet can be divided into equal halves.

Consult your doctor if your symptoms do not improve or get worse after 5 days. /.../ should not be taken longer than 4-5 days without the advice of a doctor.

If you take more /…/ than you should
So far, specific symptoms of overdose have not been reported. Based on accidental overdose and/or medication error reports the observed symptoms are consistent with the known side effects of ambroxol hydrochloride at recommended doses (see section 4). If you have accidentally taken too much of this medicine, contact your nearest hospital casualty department or your doctor immediately.

Please take this leaflet with you to the hospital or doctor so they know what has been taken.

If you forget to take /…/
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 get any of the following serious side effects, stop taking /…/ and get emergency help straight away:

Frequency not know (cannot be estimated from the 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) (see further under 'Warnings and precautions' in section 2).

Other side effects:

Common (may affect up to 1 in 10 people):
- Nausea
- Changed taste
- Numbness of the mouth or throat (hypoaesthesia)

Uncommon (may affect up to 1 in 100 people):
- Vomiting
- Dry mouth
- Diarrhoea
- Indigestion (dyspepsia)
- Stomach pain

Rare (may affect up to 1 in 1,000 people):
- Hypersensitivity reactions
- Rash, urticaria

Not known (frequency cannot be estimated from the available data):
- 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /.../

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton and tube label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30°C.
Store in the original package in order to protect from moisture.

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 /…/ contains

- The active substance is ambroxol hydrochloride. One effervescent tablet contains 30 mg ambroxol hydrochloride. One effervescent tablet contains 60 mg ambroxol hydrochloride.
- The other ingredients are: citric acid (anhydrous), sodium hydrogen carbonate, sodium carbonate (anhydrous), saccharin sodium, sodium cyclamate, sodium chloride, sodium citrate, lactose (anhydrous), mannitol, sorbitol (E 420), simeticone, cherry flavour (natural/nature identical flavouring substances, maltodextrin, mannitol (E421), gluconolactone (E575), sorbitol (E420), acacia (E414), colloidal silica (anhydrous) (E551)).

What /…/ looks like and contents of the pack
/…/ 30 mg are white round tablets, 18 mm in diameter, with a break mark on one side, engraved "3" on each tablet half and with a cherry odour. The tablet can be divided into equal doses.
/…/ 60 mg are white round tablets, 18 mm in diameter, with a break mark on one side and a cherry odour. The tablet can be divided into equal doses.
The effervescent tablets are packed into polypropylene tubes which are closed with polyethylene stoppers. The stoppers are filled with Silica gel dessicant to protect the tablets against moisture.

Pack sizes: 10 and 20 effervescent tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

Manufacturer
<[To be completed nationally]>

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

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

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

<[To be completed nationally]>