

Product information for Ambroxol and Bromhexine expectorants to be updated

02.03.2015 | Circular Number P03/2015

Information on ambroxol/bromhexine containing products

- Ambroxol and bromhexine are expectorants in syrup or tablet form which help make the mucus thinner and therefore easier to be cleared away in patients who have short- or long-term diseases of the lungs or airways.
- In some EU member states but not Malta, lozenge formulations are also available as well as formulations for injection. The injection formulation is used to treat premature and newborn babies for respiratory distress syndrome (RDS), a condition in which the baby's lungs are too immature for the baby to breathe properly. Some of these formulations are also used to increase lung maturation before birth.

In Malta the following products are authorised;

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
Ambroxol	Medovent Elixir Syrup 15mg/ml	Oral solution	PoM	AA032/08201	Medochemie Ltd.
Ambroxol	Mucobroxol Syrup	Syrup	OTC	AA197/00301	Mundipharma Pharmaceuticals Ltd.
Ambroxol	Mucolisin 30mg/5ml syrup	syrup	OTC	AA949/00101	Actavis EAD
Ambroxol	Entus Max 30mg/5ml	Syrup	OTC	AA992/00101	Aflofarm Farmacija Polska
Ambroxol	Muciclar	Syrup	OTC	MA037/00301	PIAM Farmaceutici S.P.A
Ambroxol	Muciclar	Modified release tablets	POM	MA037/00302	PIAM Farmaceutici S.P.A
Ambroxol	Mucosolvan	Syrup	POM	MA217/00101	Boehringer Ingelheim Ellas A.E
Ambroxol	Mucosolvan	Tablet	POM	MA217/00102	Boehringer Ingelheim Ellas A.E
Ambroxol	Abrolene 30mg/5ml	Syrup	POM	AA725/00502	Alet Pharmaceuticals S.A.

Ambroxol	Mucodrenol	Syrup	POM	AA1016/00501	Medinfar Consumer Health
Bromhexine hydrochloride 4mg/5ml	Bromhexine Sopharma	Syrup	POM	AA952/01301	Sopharma PLC
Bromhexine hydrochloride 4mg/5ml	Bronchotussine	Syrup	POM	MA072/00101	Adelco- Chromatourgia
Bromhexine hydrochloride 4mg/5ml	Bisolvon	Oral solution	POM	MA081/00801	Boehringer Ingelheim
Bromhexine hydrochloride 4mg/5ml	Bisolvon	Oral solution	POM	PI555/02401A	Ecosse Ltd.
Bromhexine hydrochloride 4mg/5ml	Bisolvon	Oral solution	POM	PI908/05701A	NeoFarma
Bromhexine hydrochloride BP 8mg	Flecoxin 8	Tablet	OTC	MA084/03701	Remedica Ltd.
Bromhexine hydrochloride 0.8 milligram(s)/millilitre	Tosseque 0.8mg/ml	Syrup	OTC	AA1016/00601	Medinfar Consumer Health

Information from the European Medicines Agency about the safety concern

The EMA's CMDh (a regulatory body representing the European Union (EU) Member States) has endorsed recommendations to update the product information for ambroxol- and bromhexine-containing medicines with information about the small risk of severe allergic reactions and severe cutaneous adverse reactions (SCARs). The recommendations were originally made by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), which confirmed the previously known risk of allergic reactions and also identified a small risk of SCARs, a group of skin conditions which include erythema multiforme and Stevens-Johnson syndrome.

As a result, SCARs are now to be listed as side effects in the product information for these medicines, and patients are to stop treatment immediately if symptoms of SCARs occur.

The CMDh position will now be sent to the European Commission, which will take an EU-wide legally binding decision.

For more information please visit www.ema.europa.eu

In Malta

Information to healthcare professionals

- Anaphylactic reactions and severe cutaneous adverse reactions (SCARs), including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis, have been reported in patients receiving ambroxol.

- As ambroxol is a metabolite of bromhexine, the risk of anaphylactic and severe cutaneous reactions is considered to apply also to bromhexine.
- The risk of anaphylactic reactions and SCARs with ambroxol or bromhexine is low. Frequencies of these side effects are unknown.
- Advise your patients that they should stop treatment immediately if symptoms of progressive skin rash occur.

Information to patients

- There is a small risk of allergy and skin reactions with ambroxol and bromhexine used as expectorants to clear mucus in the airways.
- If you experience allergic or skin reactions such as skin swellings or rash, stop treatment immediately and contact your doctor.
- If you are taking ambroxol or bromhexine and have any questions or concerns speak to your doctor or pharmacist.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on ambroxol/bromhexine containing medicines. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form or online at <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicine Authority website for product safety updates as these are issued on an ongoing basis.