Review of Ambroxol and Bromhexine containing medicines started

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Information on ambroxol/bromhexine containing products

- Ambroxol and bromhexine are mainly used by mouth (orally) as expectorants to help make the mucus thinner and therefore easier to be cleared away in patients with 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; 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 Syrup15mg/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
Bromhexine hydrochloride 4mg/5ml	Bromhexine Sopharma	Syrup	POM	AA952/01301	Sopharma PLC
Bromhexine hydrochloride	Bronchotussine	Syrup	POM	MA072/00101	Adelco-Chromatourgia

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4mg/5ml					
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 Tablets	Tablet	OTC	MA084/03701	Remedica Ltd.

Information from the European Medicines Agency about the safety concern

The European Medicines Agency has started a review of medicines containing ambroxol and bromhexine, which are widely used as expectorants (medicines that help clear the airways), as well as to relieve sore throat. Some formulations are used to treat breathing disorders in premature and newborn babies.

The review of ambroxol and bromhexine was requested by the Belgian medicines agency (AFMPS). This follows concerns over an increased number of reports of allergic reactions, including anaphylactic (severe allergic) reactions with ambroxol. Medicines containing ambroxol have also been linked to severe skin adverse reactions. In addition, the AFMPS was concerned about the use of ambroxol as expectorant in children below 6 years of age and considered that the benefits of these medicines did not outweigh the risks in this population. Since bromhexine gets mainly converted into ambroxol in the body, and there are some reports linking the use of bromhexine with allergic reactions, the AFMPS considered that the review should also cover medicines containing bromhexine.

The European Medicines Agency will now review the available data on the benefits and risks of medicines containing ambroxol and bromhexine, and issue an opinion on the marketing authorisations of these medicines across the European Union (EU).

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

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.

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