MUCOPECT®

DESCRIPTION

Active Moiety(ies) / Active Ingredients
Ambroxol hydrochloride

Pharmaceutical Form(s) Syrup
Composition 5 ml syrup contain 15 mg
trans-4-[(2-amino-3,5-dibromo-benzyl)amino] cyclohexanol hydrochloride (=ambroxol hydrochloride)

Excipients:
benzoic acid, hydroxyethylcellulose, sucralose, woodberry aroma, vanilla aroma, water purified.

Product Description
Clear to almost clear and colourless to almost colourless slightly viscous syrup.

INDICATIONS
As mucolytic agent in acute and chronic respiratory tract diseases particularly in chronic bronchitis exacerbation and bronchitis asthmatic.

DOSAGE AND ADMINISTRATION
Syrup 15 mg/5 ml
1 measuring spoonful = 5 ml

Children 6–12 years	:	5 ml (1 msp.) 2–3 times daily
Children 2–6 years	:	2.5 ml (1/2 msp.) 3 times daily
Children under 2 years	:	2.5 ml (1/2 msp.) 2 times daily

General:
In acute respiratory indications, medical advice should be sought if symptoms do not improve or worsen in the course of therapy.

MUCOPECT® can be taken with or without food.

CONTRAINDICATIONS
MUCOPECT® is contraindicated in patients known to be hypersensitive to ambroxol or other excipients of the formulation.

WARNINGS/PRECAUTIONS

There have been reports of severe skin reactions such as erythema multiforme, Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP) associated with the administration of Ambroxol hydrochloride. If symptoms or signs of a progressive skin rash (sometimes associated with blisters or mucosal lesions) are present, ambroxol hydrochloride treatment should be discontinued immediately and medical advice should be sought. Mostly these could be explained by the severity of the patient's underlying disease and/or concomitant medication. In addition, during the early phase of a Stevens-Johnson syndrome or TEN a patient may first experience non-specific influenza-like prodromes like e.g. fever, aching body, rhinitis, cough and sore throat. Mislead by these non-specific influenza-like prodromes it is possible that a symptomatic treatment is started with a cough and cold medication.

Therefore, if new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with ambroxol hydrochloride discontinued as a precaution.

In the presence of impaired renal function MUCOPECT® may be used only after consulting a physician.

MUCOPECT® syrup 15 mg/5 ml:

Benzoic acid
This medicine contains 8.5 mg benzoic acid in 5 ml of syrup.

INTERACTIONS
No clinically relevant unfavourable interactions with other medications are known.

REPRODUCTION
Pregnancy
Ambroxol hydrochloride crosses the placental barrier.

Nonclinical 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 MUCOPECT® is not recommended.

Lactation
Animal studies have shown that Ambroxol hydrochloride is excreted in breast milk.
Although unfavourable effects on breastfed infants would not be expected, MUCOPECT® is not recommended for use in nursing mothers.

Fertility
Clinical data on fertility is not available for ambroxol.
Nonclinical studies do not indicate direct or indirect harmful effects with respect to fertility (see Section Nonclinical Safety Data).

DRIVING A VEHICLE OR PERFORMING OTHER HAZARDOUS TASKS
There is no evidence from post marketing data 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.

ADVERSE REACTIONS
The following CIOMS frequency rating is used, when applicable:
Very common ≥ 10%; Common ≥ 1 and < 10%; Uncommon ≥ 0.1 and < 1%; Rare ≥ 0.01 and < 0.1%; Very rare < 0.01%; Not known (cannot be estimated from available data).

Related to MUCOPECT® syrup
Immune system disorder
Rare: hypersensitivity reactions
Not known: anaphylactic reactions including anaphylactic shock, angioedema, and pruritus

Nervous system disorders
Common: dysgeusia

Respiratory, mediastinal and thoracic disorders
Common: pharyngeal hypoaesthesia

Gastro-intestinal disorders
Common: nausea, hypoaesthesia oral
Uncommon: vomiting, diarrhea, dyspepsia, abdominal pain, dry mouth
Rare: dry throat

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

Reporting of suspected adverse reactions
Report immediately if you experience any adverse reaction or undesirable condition during and after using the medicinal product to farmakovigilans@kalventis.com.

OVERDOSE
No specific overdose symptoms have been reported in human.

MANAGEMENT
Based on accidental overdose and/or medication error reports the observed symptoms are consistent with the known side effects of MUCOPECT® at recommended doses and may need symptomatic treatment.

PHARMACOLOGY
Pharmacodynamics
Preclinically Ambroxol hydrochloride has been shown to increase respiratory tract secretion. It enhances pulmonary surfactant production and stimulates ciliary activity. These actions result in improved mucus flow and transport (mucociliary clearance). Improvement of mucociliary clearance has been shown in clinical pharmacologic studies. Enhancement of fluid secretion and mucociliary clearance facilitates expectoration and eases cough.

A local anaesthetic effect of ambroxol hydrochloride has been observed in the rabbit eye model which may be explained by the sodium channel blocking properties. It was shown in vitro that ambroxol hydrochloride blocks cloned neuronal sodium channels; binding was reversible and concentration dependent.

These pharmacological properties are in accordance with the ancillary observation in clinical efficacy studies for the treatment with ambroxol hydrochloride of upper respiratory tract symptoms that leads to rapid relief of pain and pain related discomfort in the ear-nose-trachea region upon inhalation.

Ambroxol hydrochloride showed an anti-inflammatory effect. Cytokine release from blood but also tissue bound mononuclear and polymorphonuclear cells was found to be significantly reduced by ambroxol hydrochloride *in vitro*.

Antiviral properties in in vitro studies and in animal models:
In in vitro studies in human tracheal epithelial cells, a reduction of rhinovirus (RV14) replication has been observed.

In a mouse airway model, a reduction of Influenza A virus replication was observed with ambroxol pretreatment.

Following the administration of ambroxol hydrochloride antibiotic concentrations (amoxicilline, cefuroxime, erythromycin) in bronchopulmonary secretions and in the sputum are increased.

Pharmacokinetics
Absorption
Absorption of all immediate release oral forms of ambroxol hydrochloride is rapid and complete, with dose linearity in the therapeutic range.

Maximum plasma levels are reached within 1 to 2.5 hours following oral administration of the immediate-release formulation and after a median of 6.5 hours for of the slow-release formulation.

Food was not found to influence the bioavailability of ambroxol hydrochloride when administered orally.

Measurement of the plasma level after repeated oral administration did not produce any indication of accumulation at therapeutic dosage.

Distribution

Distribution of ambroxol hydrochloride from blood to tissue is rapid and pronounced, with the highest concentration of the active substance found in the lungs following intravenous administration.
The volume of distribution following oral administration was estimated to be 552 L.
In the therapeutic range, plasma protein binding was found to be approximately 90%.

Metabolism
About 30% of an orally administered dose is eliminated via first pass metabolism.

Ambroxol hydrochloride is primarily metabolized in the liver by glucuronidation and some cleavage to dibromanthranilic acid (approximately 10% of dose) aside from some minor metabolites.
Studies in human liver microsomes have shown that CYP3A4 is responsible for the metabolism of ambroxol hydrochloride to dibromanthranilic acid.

Elimination
Within 3 days of oral administration, approximately 6% of the dose is found in free form, while approximately 26 % of the dose is recovered in a conjugated form in the urine.

Ambroxol hydrochloride is eliminated with a terminal elimination half-life of approximately 10 hours. Total clearance is in the range of 660 mL/min, with renal clearance accounting for approximately 8% of the total clearance.
It has been estimated that the amount of dose excreted in urine after 5 days represents about 83% of total dose (radioactivity).

Special Populations
Hepatic Impairment
In patients with hepatic dysfunction elimination of ambroxol hydrochloride is reduced, resulting in approximately 1.3 to 2-fold higher plasma levels.
Due to the wide therapeutic range of ambroxol hydrochloride, dose adjustments are not necessary.

Age/Gender
Age and gender were not found to affect the pharmacokinetics of ambroxol hydrochloride to a clinically relevant extent, and thus there is no necessity for adjustment of dosage regimens.

NONCLINICAL SAFETY DATA
Single Dose Toxicity
Ambroxol hydrochloride has a low index for acute toxicity.

Repeat Dose Toxicity
In repeated-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 levels (NOAELs). 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 (infusions 3 h/day) showed no severe local and systemic toxicity including histopathology. All adverse effects were reversible.

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

Carcinogenicity
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.

Reproductive and Developmental Toxicity

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.

Availability
Syrup 15 mg/5ml:
Bottle of 60 ml
Reg.No.

Store below 30ºC, protect from light.
Store in a safe place, out of reach of children.

Only on doctor's prescription.
Harus dengan resep dokter.

Manufactured by:
PT Menarini Indria Laboratories
Bekasi, Indonesia

For:
PT Kalventis Sinergi Farma
Jakarta, Indonesia

Under license from:
Opella Healthcare International SAS, France

Revision date: 22 September 2025 (CCDS V1)

HALAL INDONESIA ID00410000475771021

Opella.

Mucopect®

Ambroksol Hidroklorida

MUCOPECT® mengandung ambroksol hidroklorida, yang merupakan obat mukolitik (pengencer dahak) pada penyakit saluran pernapasan akut dan kronik khususnya pada bronkitis kronik eksaserbasi dan bronkitis asmatik.

Sediaan MUCOPECT®	Kekuatan	Deskripsi Produk
Sirup 	15 mg/5 ml	Sirup agak kental berwarna bening/hampir jernih, dan tidak berwarna/hampir tidak berwarna.

Zat tambahan: b*enzoic acid, hydroxyethylcellulose, sucralose, woodberry aroma, vanilla aroma, water purified.*

Dosis dan Cara Pemberian MUCOPECT®

Sediaan	Usia	Dosis	Petunjuk Penggunaan
Sirup 15mg / 5ml	Anak usia 6-12 tahun	5 ml 2 3 kali sehari	 Dapat dikonsumsi dengan atau tanpa makanan
	Anak usia 2-6 tahun	2,5 ml 3 kali sehari	 Jangan digunakan bersamaan dengan obat penekan batuk
	Anak usia <2 tahun	2,5 ml 2 kali sehari	

Cara Kerja MUCOPECT®

Ambroksol hidroklorida yang terkandung dalam **MUCOPECT®** meningkatkan produksi surfaktan paru dan menstimulasi sekresi saluran napas sehingga dapat melancarkan proses pengeluaran dahak dan memudahkan batuk.

Jangan Gunakan **MUCOPECT®** Jika alergi terhadap ambroksol hidroklorida atau komponen lain dalam formulasi

Perhatikan keadaan berikut pada penggunaan **MUCOPECT®**

- Segera berkonsultasi ke dokter apabila gejala batuk tidak membaik atau semakin memburuk
- Hindari penggunaan **MUCOPECT®** pada ganggual fungsi ginjal atau penyakit hati berat kecuali atas petunjuk dokter
- Tidak ada interaksi dengan obat lain secara klinis

Penggunaan MUCOPECT® pada Ibu Hamil dan Menyusui

Penggunaan **MUCOPECT®** pada kehamilan harus atas petunjuk dokter.

MUCOPECT® tidak dianjurkan digunakan pada ibu menyusui.

Tidak ada studi mengenai efek penggunaan **MUCOPECT®** terhadap kemampuan mengemudi dan mengoperasikan mesin yang pernah dilakukan.

MUCOPECT® dapat mempunyai efek samping yang biasa terjadi misal perubahan rasa (disgeusia), kebas pada bagian tenggorokan/kerongkongan (hipoestesia faringeal), tidak biasa terjadi seperti mual, muntah, diare, dispepsia, nyeri perut dan mulut kering. Jarang terjadi, berupa reaksi alergi, tenggorokan kering, ruam, biduran (urtikaria). Selain itu terdapat kemungkinan efek samping (belum pernah dilaporkan/diketahui) berupa reaksi alergi berat (anafilaksis), pembengkakan (angioedema), gatal-gatal (pruritus), dan reaksi alergi kulit berat (*erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis* dan *acute generalized exanthematous pustulosis).*

Pelaporan efek samping
Segera laporkan apabila Anda mengalami keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat kepada farmakovigilans@kalventis.com. Anda dapat membantu memberikan informasi terkait keamanan obat ini.

Jika memiliki gangguan ginjal, MUCOPECT® hanya dapat digunakan setelah berkonsultasi dengan dokter.

Tidak terdapat gejala spesifik overdosis yang dilaporkan terjadi pada manusia hingga saat ini. Gejala yang muncul sesuai dengan gejala efek samping **MUCOPECT®**. Jika mengalami gejala-gejala tersebut, segera berkonsultasi ke dokter.

Kemasan & Cara Penyimpanan **MUCOPECT®**
Sirup 15 mg/5ml : Botol 60 ml Reg. No. DKL1821207337A1

Simpan di bawah suhu 30° C, terlindung dari cahaya.
Simpan di tempat aman, jauhkan dari jangkauan anak-anak.

Harus dengan resep dokter.

Diproduksi oleh:
PT Menarini Indria Laboratories
Bekasi, Indonesia

Untuk:
PT Kalventis Sinergi Farma
Jakarta, Indonesia

Di bawah lisensi dari:
Opella Healthcare International SAS, France

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