PRODUCT INFORMATION
No. 0110-07

MUCOPECT®

Composition

1 tablet contains	30 mg
5 ml syrup contain	15 mg

trans-4-[(2-amino-3,5-dibromo-benzyl)amino] cyclohexanol hydrochloride (=ambroxol hydrochloride)

Excipients:
Tablets : Lactose monohydrate, Maize starch dried, Silica colloidal anhydrous, Magnesium stearate.
Syrup 15mg/5ml : Benzoic acid, Hydroxyethylcellulose, Acesulfame potassium, Sorbitol liquid, Glycerol 85%, Woodberry aroma, Vanilla aroma, Water purified.

Product Description
Tablet : Round, white tablets, both faces flat, with bevelled edge; one face is scored and impressed with '67C' above and below the score; the other face is blank.
Syrup : Clear to almost clear and colourless to almost colourless slightly viscous liquid.

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

Dosage and administration
Tablet 30 mg :
Adult and children over 12 years: 1 tablet 2–3 times daily.
Children 6-12 years: ½ tablet 2–3 times daily

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 should not be used in patients known to be hypersensitive to ambroxol hydrochloride or other components of the formulation.

In case of rare hereditary conditions that may be incompatible with an excipient of the product (please refer to Special warnings and precautions) the use of the product is contraindicated.

Special Warnings and Precautions

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 hydrochloride. 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. 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.

In patients with impaired bronchial motility and copious secretions (as seen, for instance, in the rare syndrome of primary ciliary dyskinesia), MUCOPECT should be used with caution because of the risk that they may promote accumulation of secretions.

MUCOPECT must not be used in patients with impaired renal function or severe lever disease except on medical advice. With ambroxol, as with any active substance which is metabolized in the liver and then eliminated via the kidneys, accumulation of the metabolites which are formed in the liver can be expected to occur in patients with severe renal impairment.

MUCOPECT tablets, 30 mg: One tablet contains 171 mg lactose resulting in 684 mg lactose per maximum recommended daily dose (120 mg). Patients with rare hereditary condition of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

MUCOPECT syrup 15 mg/5 ml: 5 ml syrup contain 1.2 g sorbitol resulting in 7.4 g sorbitol per maximum recommended daily dose (30 ml). Patients with rare hereditary condition of fructose intolerance should not take this medicine. It may also have a mild laxative effect.

Interactions
Concomitant administration of MUCOPECT & cough suppressant may lead to the development of a dangerous accumulation of secretions owing to attenuation of the cough reflex and should be undertaken only after careful risk-benefit assessment.

Fertility, pregnancy and lactation
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
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
Nonclinical studies do not indicate direct or indirect harmful effects with respect to fertility.

Effects on ability to drive and use machines
There is no evidence from postmarketing 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.

Side Effects
For tablets:
Immune system disorder,
Rare: hypersensitivity reactions.
Not known: anaphylactic reactions including anaphylactic shock, angioedema, pruritus.

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).

Gastro-intestinal disorders
Nausea, vomiting, diarrhea, dyspepsia and abdominal pain

For syrup:
Immune system disorder
Rare: hypersensitivity reactions.
Not known: anaphylactic reactions including anaphylactic shock, angioedema, pruritus.

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).

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

Gastro-intestinal disorders and Respiratory, mediastinal and thoracic disorders
Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, oral and pharyngeal hypoaesthesia, dry mouth and dry throat.

General disorders and administration site conditions
Uncommon : fever, mucous membrane reactions

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 MUCOPECT at recommended doses and may need symptomatic treatment.

Pharmacological properties
Preclinically Ambroxol hydrochloride, the active ingredient of MUCOPECT, 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.

Cytokine release from blood but also tissue-bound mononuclear and polymorphonuclear cells was found to be significantly reduced by ambroxol hydrochloride in vitro.

In clinical studies in patients with sore throat, pharyngeal pain and redness was significantly reduced.

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.

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.
The absolute bioavailability after a 30 mg tablet was found to be 79%.
The slow release capsule showed a relative availability of 95% (dose-normalized) in comparison to a daily dose of 60 mg (30 mg twice daily) administered as immediate-release tablet.

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. 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 and elimination:

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.
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).

Pharmacokinetics in special populations:

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 high therapeutic range of ambroxol hydrochloride, dose adjustments are not necessary.

Others:

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.

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

Toxicology

Ambroxol hydrochloride has a low index for acute 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.

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.

Availability
Tablet 30 mg:
Box contains of 10 blister @ 10 tablet
Reg.No.

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

Store below 30°C, 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 Boehringer Ingelheim Indonesia
Bogor, Indonesia

For:
PT Kalventis Sinergi Farma
Jakarta, Indonesia

Under license from:
Sanofi, France

Mucopect®

Ambroxol Hydrochloride

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
Tablet 	30 mg	Tablet bulat berwarna putih dengan kedua sisi rata bertepi miring, satu sisi diberi garis bagi tengah dan tanda '67C' di bagian atas dan bawah, dengan sisi lainnya polos
Sirup 	15 mg/5 ml	Larutan agak kental berwarna bening/hampir jernih, dan tidak berwarna/hampir tidak berwarna.

Zat tambahan:

- Tablet: *lactose monohydrate, maize starch dried, silica colloidal anhydrous, magnesium stearate.*
- Sirup: *benzoic acid, hydroxyethylcellulose, acesulfame potassium, sorbitol liquid, glycerol 85%, woodberry aroma, vanilla aroma, water purified.*

Dosis dan Cara Pemberian MUCOPECT®

Sediaan	Usia	Dosis	Petunjuk Penggunaan
Tablet 30 mg	Dewasa dan anak >12 tahun	1 tablet 2-3 kali sehari	 - Dapat dikonsumsi dengan atau tanpa makanan
	Anak usia 6-12 tahun	½ tablet 2-3 kali sehari	
Sirup 15mg/5ml	Anak usia 6-12 tahun	5 ml 2-3 kali sehari	
	Anak usia 2-6 tahun	2,5 ml 3 kali sehari	
	Anak usia <2 tahun	2,5 ml 2 kali sehari	 - Jangan digunakan bersamaan dengan obat penekan batuk

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

DISETUJUI OLEH BPOM : 26/02/2025 ID : EREG10002212400440

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 jarang terjadi, berupa reaksi alergi, ruam, biduran (urtikaria), mual, muntah, diare, dispepsia, nyeri perut, kebas pada bagian tenggorokan/kerongkongan (hipoestesia faringeal), mulut kering, tenggorokan kering, disgeusia (misal perubahan rasa), demam dan reaksi membran mukosa. Selain itu terdapat kemungkinan efek samping (belum pernah dilaporkan) 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).*

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®**

Tabet 30 mg	: Dus, 10 blister @10 tablet	Reg. No.
Sirup 15 mg/5ml	: botol 60 ml	Reg. No.

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 Boehringer Ingelheim Indonesia
Bogor, Indonesia

Untuk:
PT Kalventis Sinergi Farma
Jakarta, Indonesia

Di bawah lisensi dari:
Sanofi, France

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