Bisolvon® EXTRA

COMPOSITION

5 ml syrup contain

N-cyclohexyl-N-methyl-(2-amino-3,5-dibromobenzyl)amine hydrochloride (= bromhexine hydrochloride)	4 mg
[(2RS)-3-(2-Methoxyphenoxy)propane-1,2-diol (= guaifenesin)	100 mg

EXCIPIENTS

Sodium benzoate, aspartame, disodium edetate dihydrate, tartaric acid, peppermint flavour, FD&C yellow no.6, FD&C blue no.1, carmellose sodium, sorbitol, glycerol, purified water.

PRODUCT DESCRIPTION

Green, clear liquid with peppermint odor

PROPERTIES

BISOLVON Extra is a combination of the secretolytic agent bromhexine hydrochloride with the expectorant guaiphenesine.

Bromhexine enhances mucus transport by reducing mucus viscosity and by activating the ciliated epithelium (mucociliary clearance). In clinical studies, bromhexine showed a secretolytic and secretomotor effect in the bronchial tract area, which facilitates expectoration and eases cough.

Guaiphenesine is an expectorant agent which increases the flow of natural secretions along the lower respiratory tract.

DOSAGE AND ADMINISTRATION

Oral
Syrup 4mg/100mg per 5 ml

Recommended for age 2 years or above, with dosage recommendations :

Children 2 - 6 years:	2.5 ml 3 times daily
Children 6 - 12 years:	5 ml 3 times daily
Adults and children over 12 years:	10 ml 3 times daily

NOTE
In acute respiratory indications, medical advice should be sought if symptoms do not improve rapidly or worsen during course of therapy.

INDICATIONS/USAGE

Secretolytic and expectorant therapy to relief the cough and to ease mucus secretion.

INSTRUCTION FOR USE / HANDLING

N/A

CONTRAINDICATIONS

BISOLVON® EXTRA must not be used in patients known to be hypersensitive to bromhexine, guaifenesin or other components of the formulations.

Guaifenesin is considered to be unsafe in patients with porphyria because it has been shown to be porphyrinogenic in animals.

In case of rare hereditary conditions that may be incompatible with an excipient of the product (please refer to "Appendix Product Composition") the use of the product is contraindicated.

INTERACTIONS

Administration of bromhexine together with antibiotics (amoxicilline, cefuroxime, erythromycin, doxycycline) leads to higher antibiotic concentration.

SPECIAL WARNING AND PRECAUTIONS

BISOLVON Extra should not be used in the first trimester of pregnancy and in lactation period. Caution should be considered in patients with gastrointestinal ulcer.

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 bromhexine hydrochloride. Mostly these could be explained by the severity of the patient's underlying disease 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 prodomes like e.g. fever, aching body, rhinitis, cough and sore throat. Misled by these non-specific influenza-like prodomes 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, bromhexine hydrochloride treatment should be discontinued immediately and medical advice should be sought.

Urinary calculi have been reported in patients consuming large quantities of over-the-counter preparations containing guaifenesin. Small quantities of ephedrine were also present in the stones of one of several patients who had ingested preparations containing a combination of guaiphenesin and ephedrine.

Risks in specific populations

When using preparations containing guaifenesin, caution should be exercised in the presence of severe renal or severe hepatic impairment as there have been no specific studies of guaifenesin in subjects with renal or hepatic impairment.

Interference with laboratory tests or other diagnostic measures
The administration of guaifenesin may falsely elevate the vanilylmandelic acid (VMA) test for catechols. Hence administration of guaifenesin should be discontinued 48 hours prior to the collection of urine specimens for a vanilylmandelic acid test.
Guaifenesin administered to patients has been reported to give erroneously high values for urinary 5-hydroxyindoleacetic acid (5-HIAA).

Not recommend for children under 2 years of age.

SIDE EFFECTS

BISOLVON® EXTRA is generally well tolerated, Mild gastro-intestinal side effects have been reported with bromhexine. Allergic reactions, primarily skin rashes occur very rarely.
Increased of transaminase, headache and vertigo may also occur.

Immune system disorder, skin and subcutaneous tissue disorders and respiratory, mediastinal and thoracic

disorders.
Bromhexine: anaphylactic reaction including anaphylactic shock, angioedema, bronchospasm, rash, urticarial, pruritus, and other hypersensitivity reactions.
Guaiafenesin: Rash, including urticarial.

Gastro-intestinal disorders.
Bromhexine: diarrhoea, nausea, vomiting and abdominal pain upper.
Guaifenasin: Gastrointestinal discomfort, nausea and vomiting have occasionally been reported particularly in very large doses.

Nervous system disorders
Bromhexine: No available information
Guaifenasin: Dizziness and headache has been reported.
Abuse of medications containing guaifenesin may produce urolithiasis.

Note
Patients being treated with BISOLVON Extra should be notified of an expected increase in the flow of secretions

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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
No studies on the effect on the ability to drive and use machines have been performed with BISOLVON® EXTRA.

OVERDOSE
Symptoms
Bromhexine
No specific overdose symptoms of bromhexine 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 Bromhexine at recommended doses and may need symptomatic treatment.

Guaifenesin
The effects of acute toxicity from guaifenesin may include gastrointestinal discomfort, nausea and drowsiness.

Therapy
Bromhexine
If required, symptomatic treatment may be provided.

Guaifenesin
Treatment should be symptomatic and supportive.

APPENDIX PRODUCT COMPOSITION
BISOLVON® EXTRA

Each 5 ml syrup contains 1. Bromhexine hydrochloride 4mg 2. Guaifenesin 100mg	Safety related statements (section warnings and precautions)
Excipients	

Sorbitol	May have a mild laxative effect Calorific value 2.6 kcal/g sorbitol [80]
FD&C Yellow No. 6	May cause allergic reactions [80]
Aspartame	Contains a source of phenylalanine. May be harmful for people with phenylketonuria [80]

Presentation
Bottle of 60 ml

Reg. No. DTL1721207437A1

Store in temperature below 30°C, in a well-closed container, and do not refrigerate.
Protect from light and out of the reach of children.

P No. 1
Awas! Obat Keras
Bacalah aturan memakainya

Manufactured by:
PT Menarini Indria Laboratories,
Bekasi, Indonesia

For:
PT Kalventis Sinergi Farma,
Jakarta, Indonesia

Under licence from:
Opella Healthcare International SAS, France

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HALAL INDONESIA
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DISETUJUI OLEH BPOM: 03/03/2026

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BISOLVON® EXTRA

BISOLVON® EXTRA mengandung kombinasi sekretolitik (mukolitik) yaitu bromheksin dan ekspektoran (guaifenesin) untuk meredakan batuk berdahak dan mempermudah pengeluaran dahak.

Sediaan BISOLVON® EXTRA	Kekuatan	Deskripsi Produk
Sirup 	Bromheksin HCl 4 mg/ Guaifenesin 100 mg per 5 ml	Cairan bening berwarna hijau dengan aroma peppermint

Zat tambahan: *Sodium benzoate, aspartame, disodium edetate dihydrate, tartaric acid, peppermint flavour, FD&C yellow no.6, FD&C blue no.1, carmellose sodium, sorbitol, glycerol, purified water.*

Dosis dan Cara Pemberian BISOLVON® EXTRA

Sediaan	Usia	Dosis per hari
Sirup 4 mg/100 mg per 5 ml	Dewasa dan anak >12 tahun	3 x 10 ml
	Anak 6-12 tahun	3 x 5 ml
	Anak 2-6 tahun	3 x 2,5 ml

Cara Kerja BISOLVON® EXTRA

Bromheksin hidroklorida dapat mengurangi kekentalan dahak, melancarkan dan memudahkan proses pengeluaran dahak.

Guafenesin bekerja meningkatkan aliran sekresi alamiah di sepanjang saluran pernapasan.

Jangan Gunakan **BISOLVON® EXTRA** jika alergi/hipersensitif terhadap bromheksin hidroklorida, guaifenesin, atau komponen lain dalam formula.

Perhatikan keadaan berikut pada penggunaan **BISOLVON® EXTRA**

- Segera berkonsultasi ke dokter apabila gejala batuk tidak membaik atau semakin memburuk.
- Hati-hati penggunaan pada penderita tukak lambung kecuali atas petunjuk dokter.
- Hindari penggunaan **BISOLVON® EXTRA** pada gangguan fungsi ginjal atau penyakit hati yang berat kecuali atas petunjuk dokter
- Tidak direkomendasikan untuk anak di bawah usia 2 tahun
- Pemberian bersamaan dengan antibiotika (amoksisilin, sefuroksim, eritromisin, doksisiklin) dapat meningkatkan konsentrasi antibiotika.

Penggunaan BISOLVON® EXTRA pada Ibu Hamil dan Menyusui

Hindari penggunaan **BISOLVON® EXTRA** pada tiga bulan pertama masa kehamilan

Hindari penggunaan **BISOLVON® EXTRA** pada masa menyusui.

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

BISOLVON® EXTRA dapat mempunyai efek samping yang jarang terjadi, berupa reaksi alergi, ruam, mual, muntah, diare, nyeri perut bagian atas, pusing, sakit kepala, dan vertigo. Selain itu terdapat kemungkinan efek samping berupa reaksi alergi berat (anafilaksis), kesulitan bernapas (bronkospasme) pembengkakan (angioedema), biduran (urtikaria), gatal-gatal (pruritus), dan reaksi alergi kulit berat (*erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis dan acute generalized exanthematous pustulosis*). Pengguna **BISOLVON® EXTRA** dapat mengalami peningkatan sekresi dahak. Penyalahgunaan obat yang mengandung Guaifenesin dapat menyebabkan batu ginjal (Urolitiasis). Jika mengalami gejala-gejala tersebut, segera berkonsultasi ke dokter.

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.

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

Kemasan & Cara Penyimpanan BISOLVON® EXTRA

Dus, botol 60 ml Reg. No. xxx

Simpan pada suhu di bawah 30° C, dalam botol tertutup rapat, dan jangan disimpan di dalam lemari pendingin.

Lindungi dari cahaya dan jauhkan dari jangkauan anak-anak.

Diproduksi oleh:
PT Menarini Indria Laboratories
Bekasi, Indonesia

Untuk:
PT Kalventis Sinergi Farma,
Jakarta, Indonesia

Di bawah lisensi dari:
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