Guaifenesin Solution Orale USP

Guaifenesin Oral Solution USP

Syrup

Blokof

150 ml

150 ml

Blokof

Syrup

Guaifenesin
Oral Solution USP

Expectorant

- Relieves Chest Congestion
- Children & Adult Cough Formula

Blokof

Syrup

Expectorant

Each 5 ml Contains:

Guaifenesin USP		50 mg
Flavoured syrupy base		q.s.
Colour: Sunset Yellow		

Dosage: Adults & children 12 years and over-10 to 20 mL (2 to 4 teaspoonfuls) every 4 hours,children 6 years to under 12 years-5 to 10 mL (1 to 2 teaspoonfuls) every 4 hours,children 2 to under 6 years of age-2.5 to 5 mL (1/2 to 1 teaspoonful) every 4 hours & children under 2 years of age-consult a physician.

Store at a temperature not exceeding 30°C.
Protect from light and moisture.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

SHAKE WELL BEFORE USE

8 906056 840787

Marketed by/Commercialisé par:
GBGL Pharma Ltd.
16, Oguntona Crescent,
Gbagada Phase-1, Lagos.

Manufactured by / Fabriqué Par :
RATNAMANI HEALTHCARE PVT. LTD.
Survey No.: 750/1, Ahmedabad-Mehsana Highway,
Vill.: Indrad-382 721, Tal.: Kadi, Dist.: Mehsana,
Gujarat (INDIA).

150 ml

Blokof

Syrup

Guaifenesin
Solution Orale USP

Expectorant

- Soulage la congestion thoracique
- Les enfants et adultes Toux formule

Blokof

Syrup

Expectorant

Chaque 5 ml contient:

Guaifenesin USP		50 mg
La base sirupeux aromatisé		qsp
Couleur: jaune soleil		

Posologie: Adultes et enfants de 12 ans et plus de 10 à 20 mL (2 à 4 cuillerées à thé) toutes les 4 heures, les enfants de 6 ans à moins de 12 années de 5 à 10 ml (1 à 2 cuillerées à thé) toutes les 4 heures, les enfants de 2 à moins de 6 ans d'âge de 2,5 à 5 ml (1/2 à 1 cuillerée à café) toutes les 4 heures et les enfants de moins de 2 ans âge consulter un médecin.

Stocké à une température ne dépassant pas 30°C. Protégez contre la lumière.

GARDEZ TOUT MÉDICAMENT HORS DE LA PORTÉE DES ENFANTS.

BIEN AGITER AVANT UTILISATION.

NAFDAC REG. No. B4-8922

Mfg. Lic. No.:

Batch No.:

Mfg. Date:

Exp. Date:

RESPECTER LES DOSES PRESCRITES
RESPECT THE DOSE PRESCRIBE

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Expectorant
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BIEN AGITER AVANT UTILISATION.

8 906056 840787

RESPECTER LES DOSES PRESCRITES
RESPECT THE DOSE PRESCRIBE

NAFDAC REG. No. B4-8922
Mfg. Lic. No.:
Batch No.:
Mfg. Date:
Exp. Date:

1. Name of the medicinal product

BLOKOF SYRUP

Guaifenesin Oral Solution USP

2. Qualitative and quantitative composition

Each 5 ml Contains:

Guaifenesin USP 50 mg

Flavoured Syrupy Base q.s.

Colour: Sunset Yellow

3. Pharmaceutical form

Oral Solution

Description: A labeled 150 ml Amber Pet bottle with Alu ROPP Cap and measuring cup,containing n Orange Colored Transparent Syrupy Liquid, packed in a printed carton along with a package leaflet.

4. Clinical particulars

4.1 Therapeutic indications

Guaifenesin is used to treat coughs and congestion caused by the common cold, bronchitis, and other breathing illnesses. This product is usually not used for ongoing cough from smoking or long-term breathing problems (such as chronic bronchitis, emphysema) unless directed by your doctor. Guaifenesin is an expectorant. It works by thinning and loosening mucus in the airways, clearing congestion, and making breathing easier.

If you are self-treating with this medication, it is important to read the package instructions carefully before you start using this product to be sure it is right for you.

Cough-and-cold products have not been shown to be safe or effective in children younger than 6 years. Therefore, do not use this product to treat cold symptoms in children younger than 6 years unless specifically directed by the doctor. Some products are not recommended for use in children younger than 12 years. Ask your doctor or pharmacist for more details about using your product safely.

These products do not cure or shorten the length of the common cold. To decrease the risk for side effects, carefully follow all dosage directions. Do not give other cough-and-cold medication that might contain the same or similar ingredients (see also Drug Interactions section). Ask the doctor or pharmacist about other ways to relieve cough and cold symptoms

4.2 Posology and method of administration

Posology

Children

Although there is no specific information comparing use of Guaifenesin in children with use in other age groups, this medicine is not expected to cause different side effects or problems in children than it does in adults. However, check with your doctor before using this medicine in children who have a chronic cough, such as occurs with asthma, or who have an unusually large amount of mucus or phlegm with the cough. Children with these conditions may need a different kind of medicine. Also, Guaifenesin should not be given to children and infants younger than 2 years of age unless you are directed to do so by your doctor.

Do not give any over-the-counter (OTC) cough and cold medicine to a baby or child under 4 years of age. Using these medicines in very young children might cause serious or possibly life-threatening side effects.

Older adults

Many medicines have not been studied specifically in older people. Therefore, it may not be known whether they work exactly the same way they do in younger adults. Although there is no specific information comparing use of Guaifenesin in the elderly with use in other age groups, this medicine is not expected to cause different side effects or problems in older people than it does in younger adults.

Method of administration

Oral Solution for oral administration.

For Cough (Adults): For immediate-release formulation, oral dose of 200-400 mg should be administered for every 4 hours. The total dose should not exceed 2.4 g/day. For sustained-release formulations, oral dose of

600-1200 mg should be administered, twice daily. The maximum dose should not exceed 2.4 g/day.

For Cough (Pediatric): For immediate-release formulations, oral dose of 12 mg/kg/day should be given in 6 divided doses for infants less than 2 years old. For children aged 2-5 years, 50-100 mg oral dose of Guaifenesin should be administered every 4 hours. The maximum dose should not exceed 600 mg/day. For children 6-11 years of age, 100-200 mg oral dose of Guaifenesin should be given, every 4 hours. The maximum dose should not 1.2 g/day. 200-400 mg oral dose of Guaifenesin should be prescribed for individuals 12 years and older, every 4 hours. The maximum dose should not exceed 2.4 g/day.

For sustained-release formulations, for children aged 2-5 years, 300 mg oral dose of Guaifenesin should be administered every 12 hours. The maximum dose should not exceed 600 mg/day. For children 6-11 years of age, 600 mg oral dose of Guaifenesin should be given, every 12 hours. The maximum dose should not 1.2 g/day. 600-1200 mg oral dose of Guaifenesin should be given for individuals 12 years and older, every 12 hours. The maximum dose should not exceed 2.4 g/day.

4.3 Contraindications

Hypersensitivity to any of the ingredients

4.4 Special warnings and precautions for use

Warning:

Ask a doctor before use if you have
cough that occurs with too much phlegm (mucus)
cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if
cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

Directions

Follow dosage below or use as directed by a physician, do not take more than 6 doses in any 24-hour period.

age	dose
adults and children 12 years and over	10 to 20 mL (2 to 4 teaspoonfuls) every 4 hours
children 6 years to under 12 years	5 to 10 mL (1 to 2 teaspoonfuls) every 4 hours
children 2 to under 6 years of age	2.5 to 5 mL (1/2 to 1 teaspoonful) every 4 hours
children under 2 years of age	consult a physician

If pregnant or breast-feeding, ask a health professional before use.

Professional Note: Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillymandelic acid (VMA).
Before taking this medication, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.
Before using this medication, tell your doctor or pharmacist your medical history, especially of: breathing problems (such as emphysema, chronic bronchitis, asthma, smoker's cough), cough with blood or large amounts of mucus.
Liquid forms of this product may contain sugar and/or alcohol. Caution is advised if you have diabetes, liver disease, or any other condition that requires you to limit/avoid these substances in your diet. Ask your doctor or pharmacist about using this product safely
The liquid forms and powder packets of this medication may contain aspartame. If you have phenylketonuria (PKU) or any other condition that requires you to restrict your intake of aspartame (or phenylalanine), consult your doctor or pharmacist about using this product safely.
Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).
During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.
It is unknown if guaifenesin passes into breast milk. Discuss the risks and benefits with your doctor before breast-feeding.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist

can often prevent or manage interactions by changing how you use your medications or by close monitoring. To help your doctor and pharmacist give you the best care, be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products) before starting treatment with this product. While using this product, do not start, stop, or change the dosage of any other medicines you are using without your doctor's approval. Guaifenesin is available in both prescription and nonprescription products. Check the labels of all your medications to make sure you are not taking more than one product containing Guaifenesin. This product can affect the results of certain lab tests (such as urine levels of certain acids). Make sure laboratory personnel and all your doctors know you use this drug. Keep a list of all the products you use. Share the list with your doctor and pharmacist to reduce your risk for serious medication problems.

Laboratory Test Interactions

Guaifenesin or its metabolites may cause color interference with the VMA (vanillylmandelic acid) test for catechols. It may also falsely elevate the level of urinary 5-HIAA (5-hydroxyindoleacetic acid) in certain serotonin metabolite chemical tests because of color interference

4.6. Pregnancy and lactation

Pregnancy

Teratogenic Effects - Pregnancy Category C

Animal reproduction studies have not been conducted. Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Therefore, these products should not be used in pregnant patients unless, in the judgment of the physician, the potential benefits outweigh possible hazards.

Lactation

It is not known whether Guaifenesin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when these products are administered to a nursing woman and a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

Guaifenesin can have minor or moderate influence on the ability to drive and use machines. If patients taking Guaifenesin suffer from dizziness, headache, fatigue or nausea the ability to react may be impaired. Caution is recommended especially at the start of treatment.

4.8 Undesirable effects

Nausea or vomiting may occur. If either of these effects persist or worsen, tell your doctor or pharmacist promptly. If your doctor has directed you to use this medication, remember that he or she has judged that the benefit to you is greater than the risk of side effects. Most people using this medication do not have serious side effects. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching /swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US -Call your doctor for medical advice about side effects.

Side-effects of Guaifenesin include nausea, vomiting, formation of kidney stones, diarrhea, and constipation. Nausea and vomiting can be reduced by taking Guaifenesin with meals. The risk of forming kidney stones during prolonged use can be reduced by maintaining good hydration and increasing the pH of urine. Rarely, severe allergic reactions may occur, including a rash or swelling of the lips or face, which may require urgent medical assistance. Mild dry mouth or chapped lips may also occur when taking this medication. Drinking a glass of water is recommended each time one takes Guaifenesin.

Guaifenesin "increases the analgesic effect of paracetamol (acetaminophen) and aspirin, increases the sedative effects of alcohol, tranquilisers, sleep-pills and total anesthetics. Guaifenesin increases the effects of medication that decrease muscle tone. Guaifenesin effects are increased by lithium and magnesium."

4.9 Overdose

In massive overdosage the stomach should be emptied (emesis and/or gastric lavage) and further absorption prevented. Treatment is symptomatic and supportive.
The acute toxicity of Guaifenesin is low and overdosage is unlikely to produce serious toxic effects. In laboratory animals no toxicity resulted when Guaifenesin was administered by stomach tube in doses up to 5 grams/kg

5. Pharmacological properties

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5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Expectorants, excluding combinations with cough suppressents.

ATC code: R05CA03

Guaifenesin is an expectorant which increases the output of phlegm (sputum) and bronchial secretions by reducing adhesiveness and surface tension. The increased flow of less viscous secretions promotes ciliary action and changes a dry, unproductive cough to one that is more productive and less frequent. By reducing the viscosity and adhesiveness of secretions, guaifenesin increases the efficacy of the mucociliary mechanism in removing accumulated secretions from the upper and lower airway.

5.2 Pharmacokinetic properties

Mechanism of action/Effect:

Guaifenesin is thought to act as an expectorant by increasing the volume and reducing the viscosity of secretions in the trachea and bronchi. Thus, it may increase the efficiency of the cough reflex and facilitate removal of the secretions; however, objective evidence for this is limited and conflicting.

Absorption:

Readily absorbed from gastrointestinal tract

Elimination:

Renal, as inactive metabolites

Toxicity:

LD_{50} 1510 mg/kg (rat, oral)

5.3 Preclinical safety data

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies to assess the long-term carcinogenic and mutagenic potential or the effect on fertility in animals or humans have not been performed.

6. Pharmaceutical particulars

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6.1 List of excipients

Sr. No.	Ingredients	Grade
1	Sodium Methyl Paraben	BP
2	Sodium Propyl Paraben	BP
3	Citric Acid Monohydrate	BP
4	Sucrose	BP
5	Sucralose	BP
6	Disodium EDTA	BP
7	Sorbitol	BP
8	Liquid glucose	BP
9	Transparent Xanthan gum	BP
10	Glycerin	BP
11	Colour Sunset yellow	IHS
12	Flavor Orange Liquid	IHS
13	Purified Water	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 25°C. Protected from light and moisture

6.5 Nature and contents of container

Primary Packing: A labeled 150 ml Amber Brute Pet bottle with Alu ROPP Cap and measurin cup. **Secondary Packing:** Such 01 Bottle is packed in a printed carton along with a package leaflet

6.6 Special precautions for disposal and other handling

None.

7. Marketing Authorisation holder

GBGL Pharma Limited.