

Strepsils Cough for Chesty Cough

Ambroxol hydrochloride 15.0mg

Product Description:

An orange-yellow, circular lozenge with a characteristic orange odour.

Pharmacodynamics:

Preclinically, ambroxol 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 has been shown in clinical pharmacologic studies. Enhancement of fluid secretion and mucociliary clearance facilitates expectoration and eases cough.

Pharmacokinetics:

Ambroxol hydrochloride is a metabolite of bromhexine which is a mucolytic agent used in the treatment of respiratory disorders associated with viscid or excessive mucus. It alters the structure of mucus to decrease its viscosity and therefore, facilitate its removal by ciliary action or expectoration.

Indication:

Strepsils Cough for Chesty Cough is a mucolytic lozenge specially formulated to help in clearing the airway by thinning of excessive tenacious mucus in chesty cough.

Recommended Dosage:

Adults: Up to 6 lozenges to be sucked per day, with maximum of 2 lozenges per dose.
Children 6-12 years: Not recommended unless under the advice of a healthcare professional.
Children under 6 years: Not indicated in children under 6 years.

Route of Administration:

Oral

Contraindications:

Allergy of hypersensitivity to ambroxol or any of the ingredients listed.

Warnings and Precautions:

If symptoms persist, consult your doctor. Very rare cases of chronically associated severe skin impairments such as Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported. In most cases, these could be explained by the severity of the underlying disease or concomitant administration of another drug. In the early stages of such severe skin reactions, initially only nonspecific flu-like symptoms appear, e.g. fever, arthralgia, runny nose, cough, and sore throat. If skin or mucous membrane damage occurs, seek medical advice immediately and discontinue treatment as a

precaution.

Interactions with Other Medicaments:

Administration of ambroxol together with antibiotics (amoxicillin, cefuroxime, erythromycin, doxycycline) leads to higher antibiotic concentration in the lung tissue. No clinically relevant unfavourable interaction with other medications have been reported.

Pregnancy and Lactation:

Use in pregnancy and breastfeeding: The usual precautions regarding the use of drugs during pregnancy, especially during the first trimester, should be observed. During breastfeeding, Strepsils Cough for Chesty Cough Lozenge should be used only if absolutely necessary.

Adverse Effects/ Undesirable Effects:

Strepsils Cough for Chesty Cough is generally well tolerated. However, mild upper gastrointestinal adverse reactions such as mouth dryness, nausea, vomiting and diarrhoea have been reported. Allergic reactions have occurred rarely, primarily skin rashes and hypersensitivity.

Immune System Disorders

Frequency not known: Anaphylactic reactions including anaphylactic shock.

Skin and Subcutaneous Skin Disorders

Frequency not known: Severe skin reactions (including Stevens Johnson syndrome, Toxic epidermal necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP).

Overdose and Treatment:

No symptoms of over dosage have been reported in man to date. If they occur, symptomatic treatment should be provided.

Storage Conditions:

Store below 30°C

Dosage forms and packaging available:

A pouch of 8 lozenges
A carton of 24 x 8 lozenges
A carton of 2 x 12 lozenges

Name and address of manufacturer:

Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd.,
65 Moo 12, Lardkrabang-Bangplee Road,
Bangplee, Samutprakarn,
10540, Thailand.

Date of text revision: May 2025

Strepsils Cough for Chesty Cough

Lozenges Ambroxol Hydrochloride

PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE. KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN Keep this leaflet. You may want to read it again.

WHAT IS IN THE PACK?

An orange-yellow, circular lozenge with a characteristic orange odour. Available in unit cartons containing two blisters of 12 lozenges, and in unit pouch containing 8 lozenges.

Each lozenge contains the active ingredient Ambroxol hydrochloride 15mg.

Also contains: Anise Oil, Sweet Orange Oil Special, Menthol natural, Tartaric acid, Saccharin sodium, Sorbitol powder, Sucrose, Liquid glucose, Ponceau 4R edicol, Sunset yellow edicol, Quinoline yellow and Purified water.

WHAT IS IT FOR?

Strepsils cough for chesty cough is a mucolytic lozenge specially formulated to help in clearing the airway by thinning of excessive tenacious mucus in chesty cough.

HOW SHOULD STREPSILS COUGH FOR CHESTY COUGH BE TAKEN?

Adults:

Up to 6 lozenges to be sucked per day, with a maximum of 2 lozenges per dose.

Children 6-12 years: Not recommended unless under the advice of a healthcare professional.

Children under 6 years: Not indicated for children under 6 years. Do not exceed stated dose. The use of Strepsils cough for chesty cough without medical supervision is not intended in patients who suffer from such conditions chronically. Medical advice should be sought if the symptoms last longer than 3 days and/or if the symptoms increase in spite of treatment with Strepsils cough for chesty cough. Remember young children can choke on lozenges.

HOW DOES STREPSILS COUGH FOR CHESTY COUGH WORK?

Strepsils

Chesty Cough Lozenges contains Ambroxol hydrochloride, which is a metabolite of bromhexine which is a mucolytic agent used in the treatment of respiratory disorders associated with viscid or excessive mucus. It alters the structure of mucus to decrease its viscosity and therefore, facilitate its removal by ciliary action or expectoration.

CHECK BEFORE YOU TAKE THIS PRODUCT

Before taking Strepsils cough for chesty cough, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription or if you have, or had any liver or kidney problems. Administration of ambroxol together with antibiotics (amoxicillin, cefuroxime, erythromycin, doxycycline) leads to higher antibiotic concentration in the lung tissue. No clinically relevant unfavourable interaction with other medications have been reported.

WHEN YOU MUST NOT TAKE STREPSILS COUGH FOR CHESTY COUGH

Do not use Strepsils cough for chesty cough if you are allergic to ambroxol or any of the other ingredients listed.

If you are not sure if you have these allergies, you should raise those concerns with your doctor or pharmacist.

You should not use Strepsils cough for chesty cough after the **Expiry Date** on the carton or container.

WHILST TAKING STREPSILS COUGH FOR CHESTY COUGH

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.

Strepsils cough for chesty cough is generally well tolerated. However, mild upper gastrointestinal adverse reactions such as mouth dryness, nausea, vomiting, indigestion, bloated feeling and diarrhoea have been reported.

Serious allergic reactions have occurred rarely. Symptoms of allergic reactions may include skin rashes and hypersensitivity (difficulty in breathing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing). Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking Strepsils cough for chesty cough.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Strepsils cough for chesty cough. Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after taking Strepsils cough for chesty cough Lozenges, so that these may be properly treated. In addition, unexpected side effects, not listed above, can occur with any medicine.

WARNINGS AND PRECAUTIONS

If Symptoms persist, consult your doctor. In very few cases, severe skin disorders such as Stevens-Johnson's syndrome and toxic epidermal necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported after administration of mucolytic substances (e.g ambroxol), which in most cases could be explained by the patient's underlying disease and/or the concomitant medication. In addition during the early phase of a these severe skin disorders, a patient may first experience non-specific influenza-like prodromes (e.g. fever, aching body, rhinitis, cough and sore throat). It is possible that a symptomatic treatment is started with a cough and cold preparation due to these misleading nonspecific influenza-like prodromes. Therefore if new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with ambroxol discontinued as a precaution.

Strepsils cough for chesty cough may cause severe allergy and serious skin reactions. Stop using Strepsils cough for chesty cough and seek medical assistance immediately if you experience any of the following symptoms:

- 1) severe allergy: breathing difficulties, light headedness, skin swellings or rash
- 2) severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation

WHAT TO DO IF YOU TAKE TOO MUCH

Seek medical advice if you have taken more than the recommended or prescribed dose of Strepsils cough for chesty cough Lozenges.

USE DURING PREGNANCY AND BREASTFEEDING

Pregnancy: Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

Special care is recommended during pregnancy, especially during the first 3 months of pregnancy. The benefits of Strepsils cough for chesty cough Lozenges must be assessed against possible effects on your child.

Breastfeeding: Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication. The benefits of Strepsils cough for chesty cough Lozenges must be assessed against possible effects on your child.

PACKAGING AVAILABLE

A pouch of 8 lozenges

A carton of 24 x 8 lozenges

A carton of 2 x 12 lozenges

STORAGE CONDITION

Store in a dry place, below 30°C.

SHELF LIFE

3 years.

MANUFACTURED BY

Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd.,
65 Moo 12, Lardkrabang-Bangplee Road,
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DATE OF REVISION

May 2025