

ACTICON- dextbrompheniramine maleate, pseudoephedrine hydrochloride liquid
ACTIPHARMA, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTICON Cold & Allergy oral solution

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextbrompheniramine Maleate, 1 mg

Pseudoephedrine HCl, 30 mg

Purpose

Antihistamine

Nasal Decongestant

Uses:

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper

respiratory allergies:

- relieves sinus congestion and pressure, helps decongest sinus openings and passages
- restores freer breathing through the nose
- runny nose • sneezing • itching of the nose or throat • itchy, watery eyes • nasal congestion

Warnings:

Do not exceed recommended dosage

Do not use this product

• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

• a breathing problem such as emphysema or chronic bronchitis • glaucoma • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland

Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

When using this product

- excitability may occur, especially in children • may cause drowsiness

- alcohol, sedatives and tranquilizers may increase drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- if symptoms do not improve within 7 days or are accompanied by fever
- new symptoms occur

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

Keep out of reach of children. In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions:

- Adults and children 12 years of age and over: Take 2 teaspoonfuls (10 mL) every 4-6 hours as needed, do not exceed 4 teaspoonfuls in 24 hours, or as directed by a doctor.
- Children 6-12 years: Take 1 teaspoonful (5 mL) every 4-6 hours as needed, do not exceed 2 teaspoonfuls in 24 hours, or as directed by a doctor.
- Children under 6 years of age: consult a doctor.

Other Information:

- Tamper Evident. Do not use if inner seal is torn, cut, or opened.
- Store at controlled room temperature 15°- 30°C (59°- 86°F)
- **Avoid excessive heat or humidity.**

Inactive Ingredients:

citric acid, flavor, glycerin, methyl paraben, propylene glycol, propyl paraben, purified water, sodium citrate, sucralose

Contains the same active ingredients as Conex®*

Manufactured in the USA for ActiPharma, Inc.

Dorado, PR 00646. Tel: (787) 608-0882

*** Conex® is a registered trademark of Llorens**

Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Llorens Pharmaceutical Corp.

Packaging

NDC 63102-105-16

ACTICON®
Cold & Allergy
Oral Solution

Contains the same active ingredients as Conex®*

Purpose
Antihistamine
Nasal Decongestant

Common cold, hay fever (allergic rhinitis) or other upper
respiratory tract infections
nasal congestion
watery eyes • nasal congestion

Do not use if you are taking a monoamine oxidase inhibitor (MAOI) (certain drugs for
Parkinson's disease), or for 2 weeks after
stopping MAOI. If your prescription drug contains an MAOI, ask a doctor
before using this product.

Do not use if you have
glaucoma • heart disease • high
blood pressure • enlarged prostate
or if you are taking
sedatives, tranquilizers, or
other drugs that cause drowsiness.

Use with caution if you are
taking other drugs that cause
drowsiness, such as
antidepressants, tranquilizers,
or sedatives. Do not drink
alcohol while using this product.
Do not operate a motor vehicle
or use machinery until you know
how this product affects you.

Keep out of reach of children.
In case of overdose, seek
professional help or contact a
Poison Control Center
immediately.

Each 10 mL (1/2 oz) contains 2
teaspoonfuls (10 mL) every 4-6
hours as needed, do not exceed
2 teaspoonfuls in 24 hours as
needed.

Contains propylparaben, purified
water, propylene glycol, and
sucralose.

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ANTIHISTAMINE NASAL DECONGESTANT

Each 5 mL contains:
Dexbrompheniramine Maleate...1 mg
Pseudoephedrine HCl.....30 mg



16 Fl.oz. (474 mL)

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dexbrompheniramine Maleate, 1 mg.....
Pseudoephedrine HCl, 30 mg.....

Uses: Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- relieves sinus congestion and pressure, helps decongest sinuses
- restores freer breathing through the nose
- runny nose • sneezing • itching of the nose or throat • itchy, watery eyes • nasal congestion

Warnings:

Do not exceed recommended dosage

Do not use this product

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur • if symptoms do not improve within 7 days or are accompanied by fever • new symptoms occur

If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions:

- Adults and children 12 years of age and over: Take 2 teaspoonfuls (10 mL) every 4-6 hours as needed, do not exceed 4 teaspoonfuls in 24 hours, or as directed by a doctor.
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DRUG FACTS

Active Ingredients (in each 5 mL tsp)	Purpose
Dexbrompheniramine Maleate, 1 mg.....	Antihistamine
Pseudoephedrine HCl, 30 mg.....	Nasal Decongestant
Uses: Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies: • relieves sinus congestion and pressure, helps decongest sinus openings and passages • restores freer breathing through the nose • runny nose • sneezing • itching of the nose or throat • itchy, watery eyes • nasal congestion	
Warnings: Do not exceed recommended dosage Do not use this product • if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. Ask a doctor before use if you have • a breathing problem such as emphysema or chronic bronchitis • glaucoma • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. When using this product • excitability may occur, especially in children • may cause drowsiness • alcohol, sedatives and tranquilizers may increase drowsiness effect • avoid alcoholic beverages • use caution when driving a motor vehicle or operating machinery Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • if symptoms do not improve within 7 days or are accompanied by fever • new symptoms occur If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.	
Directions: • Adults and children 12 years of age and over: Take 2 teaspoonfuls (10 mL) every 4-6 hours as needed, do not exceed 4 teaspoonfuls in 24 hours, or as directed by a doctor. • Children 6-12 years: Take 1 teaspoonful (5 mL) every 4-6 hours as needed, do not exceed 2 teaspoonfuls in 24 hours, or as directed by a doctor. • Children under 6 years of age: consult a doctor.	
Other Information: • Tamper Evident. Do not use if inner seal is torn, cut, or opened. • Store at controlled room temperature 15°-30°C (59°-86°F) • Avoid excessive heat or humidity.	
Inactive Ingredients: citric acid, flavor, glycerin, methyl paraben, propylene glycol, propyl paraben, purified water, sodium citrate, sucralose	

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ACTICON

dexbrompheniramine maleate, pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63102-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63102-105-16	480 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/14/2016	

Labeler - ACTIPHARMA, INC. (079340948)

Registrant - ACTIPHARMA, INC. (079340948)