

COLD AND SINUS PAIN RELIEF- cold and sinus pain relief tablet
Redicare LLC

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.

Cold Tabs

Active Ingredients (in each tablet)Purpose

Acetaminophen 325 mgpain reliever/fever reducer
Guaifenesin 200 mgexpectorant
Phenylephrine HCl 5 mgdecongestant

Uses:

temporarily: ■ relieves nasal congestion associated with sinusitis ■ relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies ■ relieves sinus congestion and pressure, helps decongest sinus openings and passages ■ restores freer breathing ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive. Temporarily relieves minor aches, pains, and fever associated with: ■ headache ■ common cold ■ toothache ■ backache ■ muscular aches ■ menstrual cramps

Warnings:

Liver Warning:

This product contains Acetaminophen. Severe liver damage may occur if: ■ you take more than 8 tablets in 24 hours ■ you take with other drugs containing acetaminophen (prescription or non-prescription) ■ you have 3 or more alcoholic drinks every day while using this product.

Allergy Warning:

acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away.

Do not use:

■ with any other product containing acetaminophen; this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health

concerns. ■ for more than 10 days for pain unless directed by a doctor ■ for more than 3 days for fever unless directed by a doctor ■ when using this product do not exceed recommended dose ■ 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 MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this product.

Ask a doctor or pharmacist before use if:

■ you are taking the blood thinning drug warfarin.

Stop use and ask a doctor if:

■ symptoms do not improve ■ pain or fever persists or gets worse ■ new symptoms occur ■ redness or swelling is present ■ nervousness, dizziness or sleeplessness occur ■ symptoms do not improve within 7 days or are accompanied by a fever • cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache.

Ask a doctor before use if you have:

■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema or where cough is accompanied by excessive phlegm (mucus)

If pregnant or breast-feeding baby,

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

Adults and children 12 years of age and older: Take 2 tablets every 4 to 6 hours as needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor.

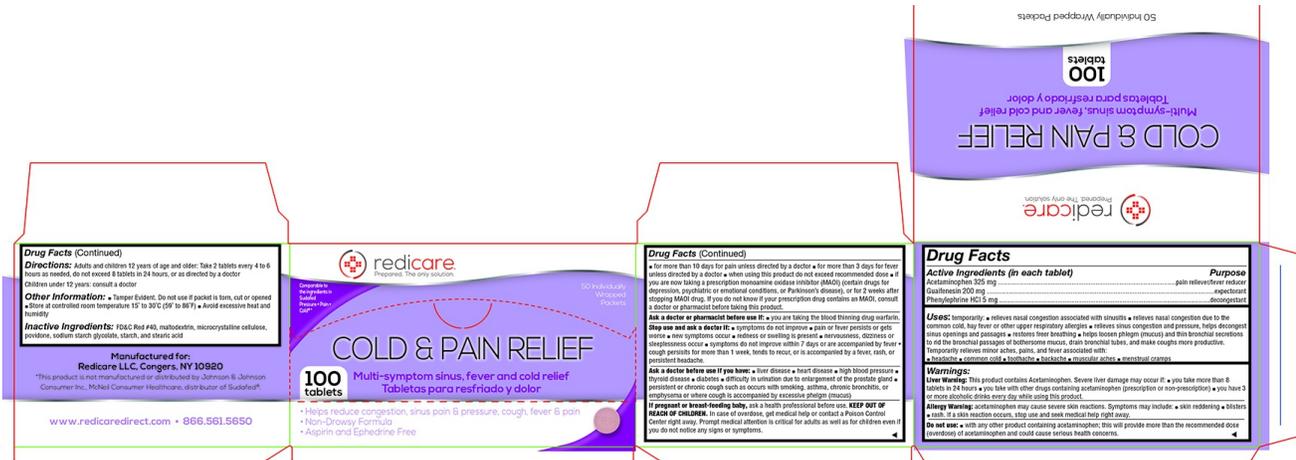
Children under 12 years: consult a doctor

Other Information

■ Tamper Evident. Do not use if packet is torn, cut or opened ■ Store at controlled room temperature 15° to 30°C (59° to 86°F) ■ Avoid excessive heat and humidity

Inactive Ingredients:

FD&C Red #40, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, starch, and stearic acid



COLD AND SINUS PAIN RELIEF

cold and sinus pain relief tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71105-106
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink (Rose Pink)	Score	no score
Shape	ROUND	Size	12mm
Flavor	CHERRY	Imprint Code	fr8
Contains			

Packaging

		Marketing Start	Marketing End
--	--	------------------------	----------------------

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71105-106-68	100 in 1 CARTON; Type 0: Not a Combination Product	10/01/2017	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/01/2017	

Labeler - Redicare LLC (800149346)