SINUS RELIEF SEVERE CONGESTION - acetaminophen,guaifenesin, phenylephrine hcl tablet
Select Corporation

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.

ACTIVE INGREDIENT

Active Ingredients	Purpose
Acetaminophen 325 mg	Pain Reliever/Fever Reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal Decongestant

PURPOSE

Pain Reliever, Fever Reducer, Expectorant, Nasal Decongestant

DOSAGE

Directions: Adults and children 12 years and over: • take 2 tablets every 4 to 6 hours as needed, do not exceed more than 8 tablets in 24 hours,or as directed by a doctor Children under 12 years: • consult a doctor

INDICATIONS

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 free 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 • with other drugs containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure. • 3 or more alcoholic drinks every day while using this product • A persistent cough may be a sign of a

serious condition

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. • 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. • 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 the recommended dose. Ask a doctor before use if you have: • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urinating due to an enlarged
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)

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 fever • cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache

PREGNANCY

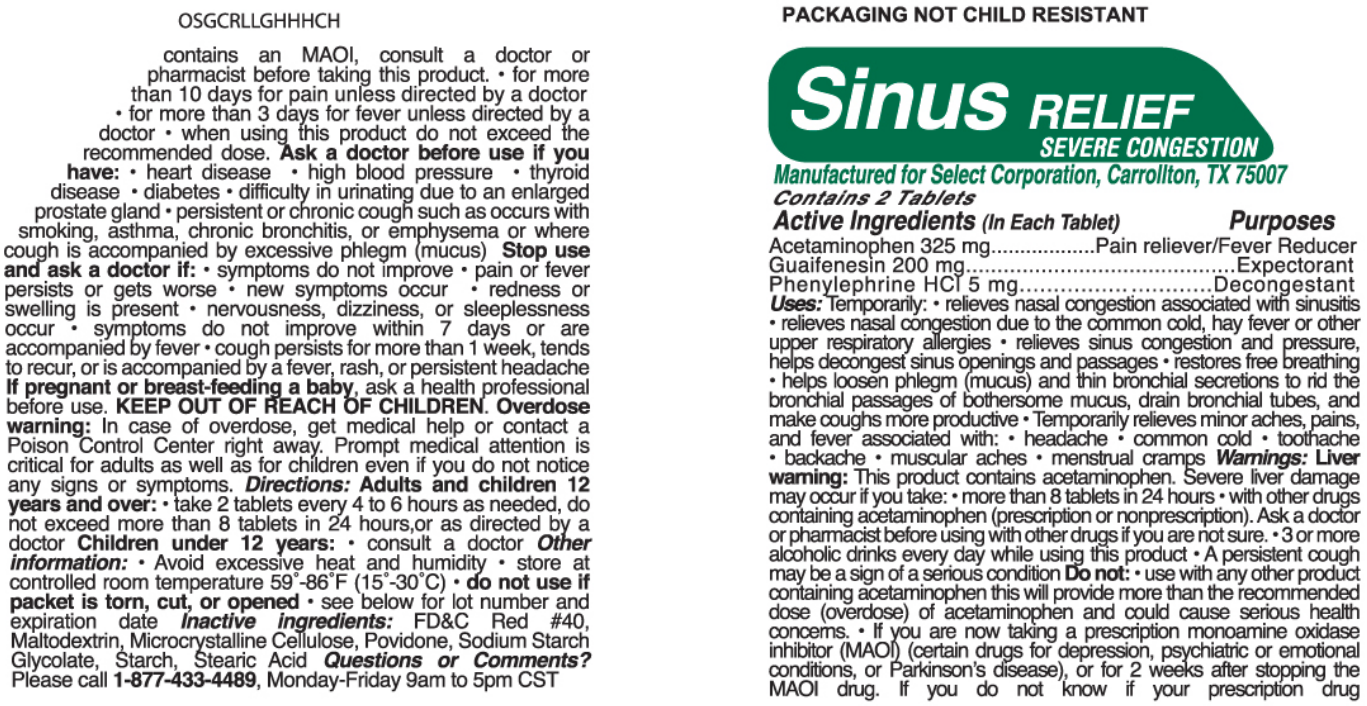
If pregnant or breast-feeding baby, ask a health professional
before use.

KEEP OUT OF REACH OF CHILDREN.

INACTIVE INGREDIENT

Inactive ingredients: FDC Red 40,
Maltodextrin, Microcrystalline Cellulose, Povidone, Sodium Starch
Glycolate, Starch, Stearic Acid

MM1



SINUS RELIEF SEVERE CONGESTION

acetaminophen,guaifenesin, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52904-455
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics

Color	pink (blossom pink)	**Score**	no score
Shape	ROUND (FR14)	**Size**	12mm
Flavor		**Imprint Code**	FR14
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-455-50	25 in 1 BOX	10/15/2012	
1	NDC:52904-455-06	1 in 1 CARTON		
1	NDC:52904-455-02	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/15/2012	

Labeler - Select Corporation (053805599)

Establishment

Name	Address	ID/FEI	Business Operations
Select Corporation		053805599	label(52904-455)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(52904-455)

Revised: 10/2012 Select Corporation