SINUS RELIEF HEADACHE NASAL - acetaminophen,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.

Drug Facts

Active Ingredients
Acetaminophen 325 mg.....Pain Reliever/Fever Reducer
Phenylephrine HCl 5 mg.....Nasal Decongestant

Pain Reliever, Fever Reducer, Nasal Decongestant

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

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. 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 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. • use more than the recommended dose

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. 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. Ask a doctor before use if you have:
• heart disease • high blood pressure • thyroid disease
• diabetes • difficulty in urination due to enlargement of the prostate gland

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

KEEP OUT OF REACH OF CHILDREN.

Inactive Ingredients: corn starch, FDC Blue 1, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, and stearic acid

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PACKAGING NOT CHILD RESISTANT

Sinus RELIEF
HEADACHE/NASAL

Manufactured for Select Corporation, Carrollton, TX 75007

Contains 2 Tablets

Active Ingredients ***(In Each Tablet)*** ***Purposes***
Acetaminophen 325 mg.....Pain reliever/Fever Reducer
Phenylephrine HCl 5 mg.....Decongestant

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. Temporarily relieves minor aches, pains, and fever associated with: • headache • common cold • toothache • backache • muscular aches • menstrual cramps ***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 • ***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 **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. • use more than the recommended dose

SINUS RELIEF HEADACHE NASAL

acetaminophen,phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52904-493
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

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 BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color	blue (sky blue)	**Score**	no score
Shape	ROUND (FR2)	**Size**	11mm
Flavor		**Imprint Code**	FR2
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52904-493-02	2 in 1 PACKET		

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)

Revised: 10/2012 Select Corporation