SINUS AND HEADACHE- acetaminophen and phenylephrine hydrochloride tablet, coated AMERISOURCE BERGEN

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.

GNP-1123B-2022-0802

Drug Facts

Active ingredients (in
each caplet)PurposeAcetaminophen 325 mgPain reliever/fever
reducerPhenylephrine HCl 5 mgNasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
 - headache
 - sinus congestion and pressure
 - nasal congestion
 - minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert

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 drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

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

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

do not take more than directed (see overdose warning)

adults and children 12	 take 2 caplets every 4 hours swallow whole; do not crush, chew, or dissolve do not take more than 10 caplets
vears and over	 do not take more than 10 caplets

Jeans and over	in 24 hours
children under 12 years	 ask a doctor

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

Compare to Tylenol® Sinus + Headache active ingredients† GOOD NEIGHBOR PHARMACY® NDC 46122-658-62 For Adults DAY Sinus + Headache Acetaminophen, Phenylephrine HCl Pain Reliever/Fever Reducer, Nasal Decongestant Relieves: • Sinus Headache • Sinus Pressure • Nasal Congestion Non-Drowsy 24 COOL TASTE CAPLETS Actual Size

	NC		GOOD NEIGHBOR PHARMACY Sinus + Headache Acetaminophen, Phenylephrine HCI Pain Reliever / Fever Reducer, Nasal Decongestant	
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SINUS AND HEADACHE

acetaminophen and phenylephrine hydrochloride tablet, coated

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	iource)	NDC:4612	2-658
Route of Administration	ORAL				
A . 11 . 1	NA . 1 . 1				
Active Ingredient/Active	моюту				
Ingre	dient Name		Basis of Str	rength	Strength
ACETAMINOPHEN (UNII: 36209ITL	9D) (ACETAMINOPHEN - UNI	ll:362O9ITL9D)	ACETAMINOPHEN		325 mg
PHENYLEPHRINE HYDROCHLORI UNII:1WS297W6MV)	DE (UNII: 04JA59TNSJ) (PHE	NYLEPHRINE -	PHENYLEPHRINE HYDROCHLORIDE		5 mg
lus stive lugare die ute					
Inactive Ingredients					
	Ingredient Name			St	rength
ACESULFAME POTASSIUM (UNII:	230V73Q5G9)				
SILICON DIOXIDE (UNII: ETJ7Z6XE	SU4)				

CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZ B9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: 08232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristi	Characteristics			
Color	green	Score	no score	
Shape	OVAL	Size	17mm	
Flavor	MINT	Imprint Code	AAA;1123	
Contains				

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122- 658-62	2 in 1 PACKAGE	10/15/2020	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
M	arketing	Information		
M	arketing Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - AMERISOURCE BERGEN (007914906)

Revised: 6/2023

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