

**ACETAMINOPHEN PHENYLEPHRINE HCL- acetaminophen 500mg phenylephrine hcl
5mg tablet**

Allegiant Health

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 ingredient

Acetaminophen 500 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever
Nasal decongestant

Uses

temporarily relieves nasal and sinus congestion temporarily relieves minor aches and pains, headaches

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 tablets in 24 hours, which is the maximum daily amount with other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product

Do Not Use

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. with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Ask 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 Doctor/Pharmacist before use if you

are taking the blood thinning drug warfarin

When Using

do not use more than directed

Stop use and ask a doctor if

redness or swelling is present new symptoms occur you get nervous, dizzy, or sleepless pain gets

worse or lasts for more than 7 days ■ fever gets worse or lasts for more than 3 days **You may report side effects to 800-952-0050**

If pregnant or Breast Feeding

ask a health professional before use

Keep Out of Reach of Children

In case of accidental overdose, contact a doctor or Poison Control Center immediately. 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 4-6 hours Do not take more than 8 tablets in 24 hours Do not use in children under 12 years of age. This will provide more than the recommended dose (overdose) and could cause serious health problems

Other information

store at room temperature in a dry place do not use if blister package is torn

Inactive Ingredients

corn starch, crospovidone, hydroxypropyl methylcellulose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid

Package/Label Principal Display Panel

ACETAMINOPHEN PHENYLEPHRINE HCL

acetaminophen 500mg phenylephrine hcl 5mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-261
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	AZ;261
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-261-99	23437 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/01/2014	

Labeler - Allegiant Health (079501930)

Registrant - Allegiant Health (079501930)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	ANALYSIS(69168-261) , LABEL(69168-261) , MANUFACTURE(69168-261) , PACK(69168-261) , RELABEL(69168-261) , REPACK(69168-261)

Revised: 9/2014

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