

ACETAFLU NIGHTTIME EFFERVESCENT- acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, effervescent

Advanced Pharmaceutical Services, Inc. Db a Affordable Quality Pharmaceuticals

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 ingredients (in each tablet)

Purposes

Acetaminophen 650 mg.....	Pain reliever/fever reducer
Diphenhydramine Hydrochloride 25 mg.....	Antihistamine/ Cough suppressant
Phenylephrine Hydrochloride 10 mg.....	Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains • minor sore throat pain • headache
- nasal and sinus congestion • cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 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

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use • in a child under 12 years of age • if you are allergic to acetaminophen

- 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.

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 • cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema

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. avoid alcoholic drinks marked drowsiness may occur.

Alcohol, sedatives and tranquilizers may increase drowsiness be careful when driving a motor vehicle or operating machinery

excitability may occur, especially with children.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs • fever gets worse or lasts more than 3 days

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13411-841
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	
ASPARTAME (UNII: Z0H242BBR1)	
POVIDONE K30 (UNII: U725QWY32X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND (TABLET)	Size	3mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13411-841-16	4 in 1 BOX	03/24/2020	
1		4 in 1 BLISTER PACK; 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	03/24/2020	

Labeler - Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals (187498279)

Establishment

Name	Address	ID/FEI	Business Operations
S.P.M CORPORATION		555279715	manufacture(13411-841)

Revised: 3/2020

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