

ACETAFLU DAYTIME EFFERVESCENT- acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, effervescent

Advanced Pharmaceutical Services, Inc. DbA 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
Dextromethorphan hydrobromide 20 mg.....	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

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs • fever gets worse or lasts more than 3 days
- redness or swelling is present • new symptoms occur • symptoms do not get better or worsen
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with fever, rash or headache that lasts. These could be signs or serious condition.

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

KEEP OUT OF REACH OF CHILDREN.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- do not take more than the the recommended dose
- adults and children 12 years and over: take 1 tablet fully dissolved in 8 oz of water every 4 hours. Do not exceed 6 tablets in 24 hours or as directed by a doctor
- children under 12 years: do not use

Other information

- each tablet contains: sodium 272 mg
- store at room temperature. Avoid excessive heat

Inactive ingredients

mannitol, aspartame, kollidon 30, citric acid, tween 20, sodium citrate, sodium bicarbonate, sodium carbonate, flavors, polyethylene glycol, dimethicone

Product Label

AcetaFlu
SEVERE COLD & COUGH
EFFERVESCENT TABLET

NDC 13411-840-16

AcetaFlu
SEVERE COLD & COUGH
EFFERVESCENT TABLET

AcetaFlu
Daytime
SEVERE COLD & COUGH

ACETAMINOPHEN • PAIN RELIEVER/FEVER REDUCER
DEXTROMETHORPHAN HBR • COUGH SUPPRESSANT
PHENYLEPHRINE HCL • NASAL DECONGESTANT

Nasal & Sinus Congestion
Cough • Body Ache
Sore Throat Pain
Headache • Fever

Infused with Ginger
Lemongrass & Lemon

16 Effervescent Tablets

Batch No:
Mfg. date:
Exp. date

31 13411 08381 5

Drug Facts

Active ingredients (in each Tablet)

Active ingredients (in each Tablet)	Pain reliever/fever reducer	Purposes
Acetaminophen 325 mg	Yes	Pain relief/fever reducer
Dextromethorphan HBr 10 mg	No	Cough suppressant
Phenylephrine HCl 10 mg	No	Nasal decongestant

Uses

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

Warnings

Use warnings: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 grams in 24 hours, which is the maximum daily dosage
- with other drugs containing acetaminophen - 3 or more alcohol drinks every day while using this product

Some throat lozenges, if used throat lozenges, periods for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use - 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) (sertraline, desipramine, pargoline, or phenelzine) or have taken one in the last 14 days, or if you are taking a prescription drug containing MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- kidney disease
- high blood pressure
- thyroid disease
- diabetes
- had or had a heart attack or a blocked coronary artery
- 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 above warning drug warnings

When using this product - do not exceed recommended dosage

Stop use and ask a doctor if

- fever remains, if persists, or develops or occurs
- fever gets worse or lasts more than 3 days
- redness or swelling (hoarseness), new symptoms occur
- symptoms do not get better or worsen
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with fever, rash or headache that lasts. These could be signs of serious reaction

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

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- Do not take more than the recommended dose.
- Adults and children 12 years and over take 1 tablet fully dissolved in 8 oz of hot water every 4 hours. Do not exceed 6 tablets in 24 hours or as directed by a doctor.
- Children under 12 years: Do not use.

Other information

- Each tablet contains sodium 272 mg.
- Store at room temperature. Avoid excessive heat.

Contains ingredients: mannitol, croscarmellose, kollidon 30, citric acid, tween 20, sodium citrate, sodium bicarbonate, sodium carbonate, flavors, polyethylene glycol, dimethicone.

Questions or comments?
call 1-800-454-5560 (Mon - Fri 9AM - 5PM PST)

Distributed by:
Affordable Quality Pharmaceuticals
Garden Grove • CA 92641 • USA

100% AQ BRANDS

ACETAFLU DAYTIME EFFERVESCENT

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13411-840
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 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:13411-840-16	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(13411-840)

Revised: 3/2020

Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals