ACETAMAX PM- acetaminophen,diphenhydramine 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.

AcetaMax PM

Active Ingredients

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

- Fever Reducer/Pain Reliever
- Nighttime sleep aid

Uses

- temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

Warnings

Liver warning: This product contains acetaminophen. 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.
• with any other product containing diphenhydramine, even one used on skin
• in children under 12 years of age
• if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have
• a sodium-restricted diet.
• liver disease
• a breathing problem such as emphysema or chronic bronchitis
• trouble urinating due to an enlarged prostate gland
• glaucoma

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

When using this product
• drowsiness will occur
• avoid alcoholic drinks
• do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

• sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
• pain gets worse or lasts more than 10 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.

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

Keep out of reach of children.

Directions

Do not take more than directed (see overdose warning)
Adults and children 12 years and over:
• take 2 tablets fully dissolved in 8oz of water at bedtime.
• do not take more than 2 tablets of this product in 24 hours

Children under 12 years: do not use

Other information

Each tablet contains:
Sodium 192 mg
Store at room temperature 68 F-77 F (20oC-25oC)

Inactive Ingredients

anhydrous citric acid, dimethicone, flavors, mannitol, polyethylene glycol 6000, polysorbate 20, povidone K30, silicon dioxide, sodium bicarbonate, sodium carbonate, sodium citrate, sucralose

Image


—AQ BRANDS—
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PM
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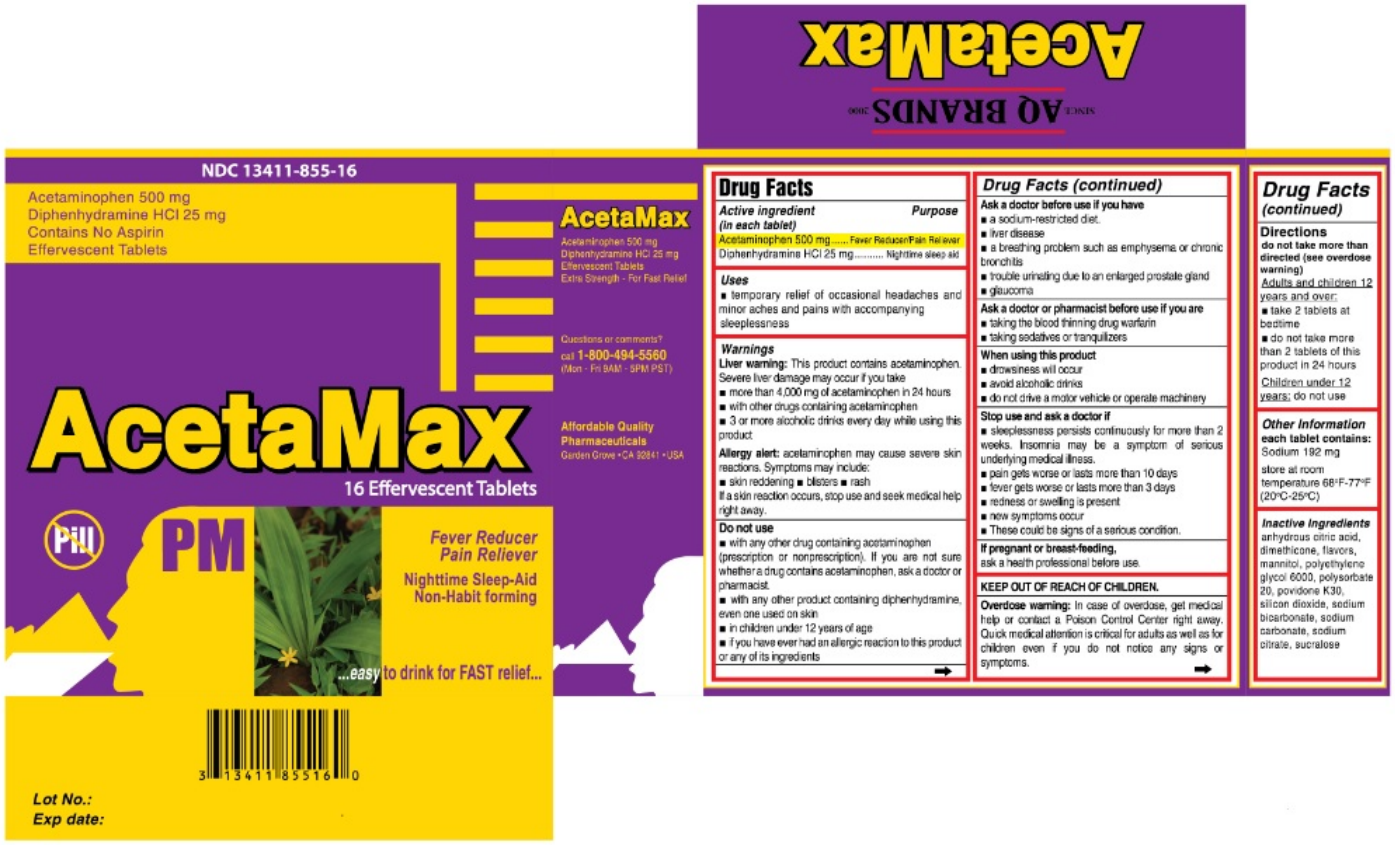
Diphenhydramine HCl 25 mg
Fever Reducer / Pain Reliever
Nighttime sleep aid
Effervescent tablet



ACETAMAX PM

acetaminophen,diphenhydramine hcl tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13411-855
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE (UNII: 8GTS82S83M) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

SODIUM CARBONATE (UNII: 45P3261C7T)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	22mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13411-855-16	16 in 1 BOX	08/31/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:13411-855-20	20 in 1 BOX	08/31/2020	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:13411-855-24	24 in 1 BOX	08/31/2020	
3		1 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 not final	part343	08/31/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations
S.P.M CORPORATION		555279715	manufacture(13411-855)

Revised: 8/2020 Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals