ACETAMAX- acetaminophen 500 mg 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

Active Ingredient

Acetaminophen 500 mg

Purpose

Pain reliever/ Fever Reducer

Uses

temporarily relieves minor aches and pains due to:

- headache
- backache
- toothache
- the common cold
- minor pain of arthritis
- muscular aches
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Alcohol warning: if you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/ fever reducers.

Acetaminophen may cause liver damage.

Do not use with any other product containing acetaminophen

Ask a doctor before use if you have

- a sodium-restricted diet
- any liver, kidney, or heart disease
- high blood pressure

Ask a doctor or pharmacist before use if you are

- allergic or sensitive to any tablet ingredients
- pregnant, breastfeeding or may become pregnant
- When using this product
- do not exceed the recommend dosage

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days.

If pregnant, may become pregnant, or breastfeeding, ask a health professional before use.

KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center immediately. 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 years and over

- take two tablets fully dissolved in 8 oz of water every 4 to 6 hours as needed.
- do not take more than 8 tablets in 24 hours.
- do not use more than 10 days unless directed by a doctor.

Children under 12 years do not use this adult product; this will provide more than the dose (overdose) of pain reliever and may cause liver damage.

Other information

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

Inactive Ingredients

anhydrous citric acid, dimethicone, docusate sodium, flavors, ginger oil, lemongrass oil, mannitol, polyethylene glycol 6000, povidone K30, silicon dioxide, sodium bicarbonate, sodium carbonate, sodium chloride, sodium citrate, sucralose, sucrose.

Image





ACETAMAX

acetaminophen 500 mg tablet, effe	ervescent				
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source))	NDC:13411	1-854
Route of Administration	ORAL				
Active Ingredient/Active Moie	ety				
Ingredient Name Basis of Stre				trength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHI			PHEN	500 mg	
Inactive Ingredients					
	Ingredient Name			St	rength
ANHYDRO US CITRIC ACID (UNII: XF4	17D3PSL)				
DIMETHICO NE (UNII: 92RU3N3Y1O)					
DOCUSATE SODIUM (UNII: F05Q2T2J	A0)				
GINGER OIL (UNII: SAS9Z1SVUK)					

WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	
MANNITOL (UNII: 30WL53L36A)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product CharacteristicsColorwhiteScoreno scoreShapeROUNDSize22mmFlavorImprint CodeImprint CodeImprint CodeContainsImprint CodeImprint CodeImprint Code

Packaging

-	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13411-854-16	16 in 1 BOX	08/31/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:13411-854-20	20 in 1 BOX	08/31/2020	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:13411-854-24	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(13411-854)	

Revised: 8/2020

Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals