AEROTAB NON-ASPIRIN- acetaminophen 500mg es tablet Aero Healthcare

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.

Aerotab Non-Aspirin Tablets

Acteminophen 500 mg

Pain reliever / fever reducer

USES

temporary relief of minor aches and pains associated with

- common cold
- headache
- toothache
- muscular aches
- backache
- arthritis
- menstrual cramps
- temporarily reduces fever

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4000 mg of acetaminophen in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy Warning: 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

- 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.

Ask a doctor before use if you have liver disease.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- symptoms do not improve
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- redness or swelling is present
- a rare sensitivity reaction occurs

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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

DIRECTIONS

- take only as directed see Overdose warning
- do not take more than 8 tablets in any 24 hour period
- do not use more than 10 days unless directed to do so by a doctor

Adults and children 12 years and over: take 2 tablets every 4 to 6 hours.

Children under 12 years of age: do not use this extra strength product. This will provide more than the recommended dose (overdose) and could cause serious health problems.

OTHER INFORMATION

Tamper evident. Do not use if packet is torn, cut or opened. Store between 20°-25°C (68°-77°F). Read all warnings and directions before use.

INACTIVE INGREDIENTS

corn starch, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

AEROTAB

Non-Aspirin

acetaminophen 500mg

Fever reducer

Pain Reliever

Relieves aches

2 per packet



AERO HEALTHCARE – US PACKAGING PROGRAM BATCH 1 | PART THREE (REVISIONS)



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AERO HEALTHCARE – US PACKAGING PROGRAM BATCH 1 | PART THREE (REVISIONS)



(USES: For the temporary relief of minor aches and pain associated with headache, common cold, mentual cramps and for the reduction of fever. WARNINGS: Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take: more than 8 tablets in 24 hours a with other drugs containing acetaminophen a 3 or more alcoholic drinks every day while using this product. Ask a doctor before use if you have liver I disease. KEEP OUT PREACH OF CHILDREN. In case of overdose, get medical help or contact a Poisson Control Center right away. If pregnant or breast-feeding, ask a health professional before use. DIRECTIONS: Adults: 2 tablets every 4 to 6 hours, not to exceed 8 tablets in any 24 hour period. Children under 12 years: ask a doctor. See box for complete product information. Mig. for. Aero Healthcare, Valley Cottage, IN 10889. ATINADOTY.

x 2.4" Overall Dimensions: 1.5" x 2.4" .9" Cavity Area: 1.125" x 1.9" 1.75" Max Print Area: 1.075" x 1.75"

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55305-126
FIGURE IVE	HONAN OTC BROG	itelii code (30dice)	1100.33303 120

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 500 mg

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)			
POVIDONE (UNII: FZ 989GH94E)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
STARCH, CORN (UNII: O8232NY3SJ)			

Product Characteristics			
Color	white	Score	score with uneven pieces
Shape	ROUND	Size	12mm
Flavor		Imprint Code	
Contains			

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55305-126- 02	25 in 1 BOX	10/31/2017			
1	NDC:55305-126- 01	2 in 1 PACKET; Type 0: Not a Combination Product				
2	NDC:55305-126- 04	50 in 1 BOX	10/31/2017			
2	NDC:55305-126- 01	2 in 1 PACKET; Type 0: Not a Combination Product				
3	NDC:55305-126- 05	125 in 1 BOX	10/31/2017			
3	NDC:55305-126- 01	2 in 1 PACKET; 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	10/31/2017	

Labeler - Aero Healthcare (008186174)

Registrant - Aero Healthcare (008186174)

Revised: 5/2023 Aero Healthcare