

AEROTAB PAIN RELIEVER- pain reliever 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 Pain Reliever

ACTIVE INGREDIENT

Drug Facts

Active Ingredients (per tablet)

Acetaminophen 500mg

Caffeine 65mg

PURPOSE

Acetaminophen 500mg.....Pain Reliever / Fever Reducer

Caffeine 65mg.....Pain Reliever Aid

USES

Temporarily relieves minor aches and pains due to:

- headaches
- muscular aches

WARNINGS

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.

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

- more than 8 caplets 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

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause

nervousness, irritability, sleeplessness, and occasionally, rapid heartbeat.

Do not use

- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or non-prescription). 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

- any new symptoms occur
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days.

These could be signs of a serious condition.

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

Keep out of reach of children. In case of overdose, get medical help or contact a 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

- do not use more than directed
- **adults and children 12 years and over:** take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- **children under 12 years:** ask a doctor

Other Information

- Store at 20-25 C (68-77 F)
- do not use if pouch is torn or open

Inactive Ingredients

corn starch, croscarmellose sodium, crospovidone, D&C red #27 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide.

Questions or comments?

Call 1-845-618-7037

AEROTAB

Pain Reliever

fever reducer

Acetaminophen 500mg

Caffeine 65mg

Extra Strength

Relieves aches and pains

Fever reducer

2 per packet



AERO HEALTHCARE
HEALTHCARE, WE MAKE IT BETTER

CODE: V3ATPR250 BX DATE: 06/07/2022 DIMENSIONS: 114mm W x 129.5mm H x 81.28mm D

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



Drug Facts

ACTIVE INGREDIENTS (per tablet)	PURPOSE
Acetaminophen 500mg	Pain Reliever / Fever Reducer
Caffeine 65mg	Pain Reliever Aid

USES
Temporarily relieves minor aches and pains due to: • headaches • muscular aches

WARNINGS
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin redness • hives • rash. If a skin reaction occurs, stop use and seek medical help right away.
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than 8 capsules 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.
Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.
Do not use • if you are allergic to acetaminophen • with any other drug containing acetaminophen (prescription or non-prescription). 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.

PAIN RELIEVER
fever reducer

Acetaminophen 500mg, Caffeine 65mg

PAIN RELIEVER
fever reducer

Acetaminophen 500mg, Caffeine 65mg

Extra strength
Relieves aches and pains
Fever reducer

Extra strength
Relieves aches and pains
Fever reducer

100
2 per packet

Drug Facts (continued)

Stop use and ask a doctor if • any new symptoms occur • painful areas in red or swollen • pain gets worse or lasts for more than 10 days • fever gets worse or lasts for more than 3 days. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a 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 • do not use more than directed • **adults and children 12 years and over:** take 2 capsules every 6 hours; not more than 8 capsules in 24 hours • **children under 12 years:** ask a doctor.

Other information • store at 20-25°C (68-77°F) • do not use if pouch is torn or open.

Inactive ingredients corn starch, croscarmellose sodium, croscopolone, D&C red #2 aluminum lake, FD&C yellow #6 aluminum lake, hydroxylose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide.

Questions or comments? Call 1-845-618-7037



AERO HEALTHCARE. WE MAKE IT BETTER.
Manufactured for AERO HEALTHCARE
US Valley Cottage, NY 10589
www.aerohealthcare.us.com
MADE IN USA

REF Code ATRP100US
V4.ATRP100US.BX
Store in a cool, dry place.

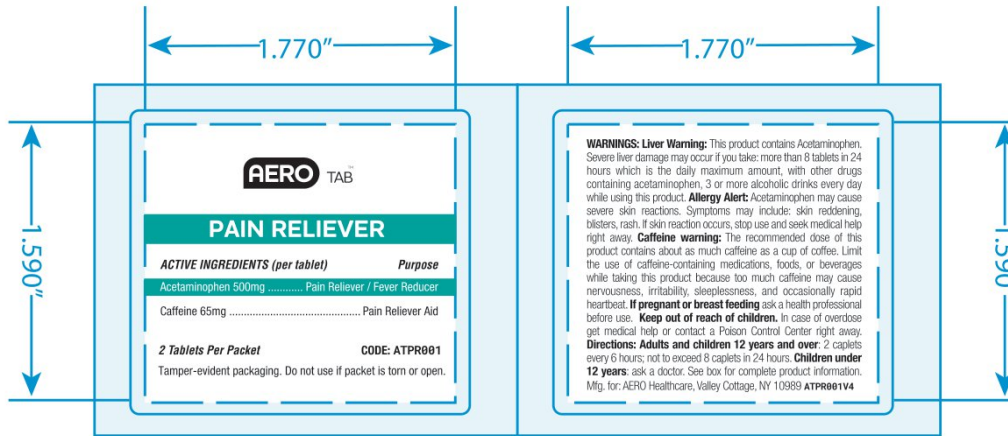
AERO HEALTHCARE. WE MAKE IT BETTER.
CODE: V4.ATRP100US.BX
DATE: 06/07/2022
DIMENSIONS: 110mm W x 90mm H x 65mm D




HEALTHCARE. WE MAKE IT BETTER.
 CODE: V3.ATPR50.BX DATE: 06/07/2022 DIMENSIONS: 110mm W x 90mm H x 65mm D

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

Pouch Size: 22
 Overall Dimensions: 2" x 2.4"



AEROTAB PAIN RELIEVER

pain reliever tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55305-127
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	red	Score	score with uneven pieces
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55305-127-02	25 in 1 BOX	11/01/2022	
1	NDC:55305-127-01	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:55305-127-04	50 in 1 BOX	11/01/2022	
2	NDC:55305-127-01	2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:55305-127-05	125 in 1 BOX	11/01/2022	
3	NDC:55305-127-01	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	11/01/2022	

Labeler - Aero Healthcare (008186174)

Registrant - Aero Healthcare (008186174)

Revised: 3/2023

Aero Healthcare