

APHEN- acetaminophen tablet
Asclemed USA, Inc.

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen 325mg

Purpose

Pain reliever/fever reducer

Uses

temporary relieves of minor aches and pains due to:

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

Warnings

Liver Warning: This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 non-prescription). If

you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if user has liver disease.

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present.

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.

Overdose warning: 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

Adults and children 12 years of age and older: take 2 tablets every 4 to 6 hours while symptoms last. Do not take more than 10 tablets in 24 hours, unless directed by a doctor. Do not use for more than 10 days unless directed by a doctor.

Children 6 years to under 12 years: take 1 tablet every 4 to 6 hours while symptoms last. Do not take more than 5 tablets in 24 hours. Do not use for more than 5 days unless directed by a doctor.

Children under 6 years of age: ask a doctor.

Other information

- store at room temperature 20°–25°C (68°– 77°F)
- do not use if imprinted safety seal under cap is broken or missing
- you may report side effects to (310) 320-0100

Inactive ingredients

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

Principal Display Panel

NDC 76420-372-15

Regular Strength
Pain Relief

AphenTM
Acetaminophen 325 mg

150 tablets

Distributed by **Enovachem**
PHARMACEUTICALS
Torrance, CA 90501

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

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Allergy alert: Acetaminophen may cause severe skin reactions.
 Symptoms may include: ■ skin redness ■ 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 non-prescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ If you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has liver disease
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Drug Facts (continue under label)



Lot: Exp:



Drug Facts (continued)

Stop use and ask a doctor if ■ pain gets worse or lasts more than 10 days in adults ■ pain gets worse or lasts more than 5 days in children under 12 years ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present. 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.
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Inactive ingredients corn starch, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

* This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol®.

Acetaminophen 325mg

APHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76420-372
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3S)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (Round)	Size	10mm
Flavor		Imprint Code	AZ;010
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-372-15	150 in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/04/2020	

Labeler - Asclemed USA, Inc. (059888437)

Revised: 10/2023

Asclemed USA, Inc.