

ACETAMINOPHEN 500 MG- acetaminophen tablet
ASCLEMED USA INC.

ACETAMINOPHEN 500 MG TABLET

Drug Facts

Active ingredient (in each tablet)

Acetaminophen USP, 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves 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. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen 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

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.

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

- pain gets worse or lasts more than 10 days
- 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: Taking more than the recommended dose (overdose) may cause liver damage. 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.

Directions

do not take more than directed (see overdose warning)

adults & children 12 years and over:

- take 1 tablet every 3-4 hours or 2 tablets every 6 hours while symptoms last
- do not take more than 8 tablets in 24 hours

children under 12 years: do not use

Other information

- store at 15° to 30°C (59° to 86°F)

Inactive ingredients

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

Questions or comments?

call **516-341-0666**, 8:30 am - 4:30 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark **TYLENOL®**.

Relabeled and Repackaged by:

Enovachem PHARMACEUTICALS

Torrance, CA 90501

Relabeled By:

Enovachem

PHARMACEUTICALS

379 Van Ness Ave.
Suite 1403-1405
Torrance, CA 90501

Acetaminophen USP 500 mg

NDC: 76420-488-10

Qty: 10

Distributed By:

Reliable 1 Laboratories LLC

Source NDC: 69618-011-XX

Source NDC: 69618-011-XX

Description: white:round/AP:013

Lot #: 00000000

Exp:

Batch #: 00000000

Drug Status: OTC

(01) 0 0376420 48810 1

(17)

(10) 00000000

(21)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.

KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

Acetaminophen USP 500 mg
NDC: 76420-488-10
S/N:
Qty: 10

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NDC: 76420-488-10
S/N:
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Acetaminophen USP 500 mg
NDC: 76420-488-10
S/N:
Qty: 10

Relabeled By:

Enovachem

PHARMACEUTICALS

379 Van Ness Ave.
Suite 1403-1405
Torrance, CA 90501

Acetaminophen USP 500 mg

NDC: 76420-488-01

Qty: 100

Distributed By:

Reliable 1 Laboratories LLC

Source NDC: 69618-011-01

Source NDC: 69618-011-01

Description: white:round/AP:013

Lot #: 00000000

Exp:

Batch #: 00000000

Drug Status: OTC

(01) 0 0376420 48801 9

(17)

(10) 00000000

(21)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.

KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

Acetaminophen USP 500 mg
NDC: 76420-488-01
S/N:
Qty: 100

Acetaminophen USP 500 mg
NDC: 76420-488-01
S/N:
Qty: 100

Acetaminophen USP 500 mg
NDC: 76420-488-01
S/N:
Qty: 100

Relabeled By:

Enovachem

PHARMACEUTICALS

379 Van Ness Ave.
Suite 1403-1405
Torrance, CA 90501

Acetaminophen USP 500 mg

NDC: 76420-488-20

Qty: 20

Distributed By:

Reliable 1 Laboratories LLC

Source NDC: 69618-011-XX

Source NDC: 69618-011-XX

Description: white:round/AP:013

Lot #: 00000000

Exp:

Batch #: 00000000

Drug Status: OTC

(01) 0 0376420 48820 0

(17)

(10) 00000000

(21)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.

KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

Acetaminophen USP 500 mg
NDC: 76420-488-20
S/N:
Qty: 20

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NDC: 76420-488-20
S/N:
Qty: 20

Acetaminophen USP 500 mg
NDC: 76420-488-20
S/N:
Qty: 20

Relabeled By:

Enovachem

PHARMACEUTICALS

379 Van Ness Ave.
Suite 1403-1405
Torrance, CA 90501

Acetaminophen USP 500 mg

NDC: 76420-488-30

Qty: 30

Distributed By:

Reliable 1 Laboratories LLC

Source NDC: 69618-011-XX

Source NDC: 69618-011-XX

Description: white:round/AP:013

Lot #: 00000000

Exp:

Batch #: 00000000

Drug Status: OTC

(01) 0 0376420 48830 9

(17)

(10) 00000000

(21)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.

KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

Acetaminophen USP 500 mg
NDC: 76420-488-30
S/N:
Qty: 30

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NDC: 76420-488-30
S/N:
Qty: 30

Acetaminophen USP 500 mg
NDC: 76420-488-30
S/N:
Qty: 30

Relabeled By:

Enovachem

PHARMACEUTICALS

379 Van Ness Ave.
Suite 1403-1405
Torrance, CA 90501

Acetaminophen USP 500 mg

NDC: 76420-488-60

Qty: 60

Distributed By:

Reliable 1 Laboratories LLC

Source NDC: 69618-011-XX

Source NDC: 69618-011-XX

Description: white:round/AP:013

Lot #: 00000000

Exp:

Batch #: 00000000

Drug Status: OTC

(01) 0 0376420 48860 6

(17)

(10) 00000000

(21)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.

KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

Acetaminophen USP 500 mg
NDC: 76420-488-60
S/N:
Qty: 60

Acetaminophen USP 500 mg
NDC: 76420-488-60
S/N:
Qty: 60

Acetaminophen USP 500 mg
NDC: 76420-488-60
S/N:
Qty: 60

Relabeled By:

Enovachem

PHARMACEUTICALS

379 Van Ness Ave.
Suite 1403-1405
Torrance, CA 90501

Acetaminophen USP 500 mg

NDC: 76420-488-90

Qty: 90

Distributed By:

Reliable 1 Laboratories LLC

Source NDC: 69618-011-XX

Source NDC: 69618-011-XX

Description: white:round/AP:013

Lot #: 00000000

Exp:

Batch #: 00000000

Drug Status: OTC

(01) 0 0376420 48890 3

(17)

(10) 00000000

(21)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.

KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

Acetaminophen USP 500 mg
NDC: 76420-488-90
S/N:
Qty: 90

Acetaminophen USP 500 mg
NDC: 76420-488-90
S/N:
Qty: 90

Acetaminophen USP 500 mg
NDC: 76420-488-90
S/N:
Qty: 90

ACETAMINOPHEN 500 MG

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76420-488(NDC:69618-011)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	AP;013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-488-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2025	
2	NDC:76420-488-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2025	
3	NDC:76420-488-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2025	
4	NDC:76420-488-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2025	
5	NDC:76420-488-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2025	
6	NDC:76420-488-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2025	



ACETAMINOPHEN 500mg Tablet

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/01/2015	

Labeler - ASCLEMED USA INC. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-488) , repack(76420-488)

Revised: 10/2025

ASCLEMED USA INC.