

ACETAMINOPHEN- acetaminophen tablet extended release tablet, extended release

Asclemed USA, Inc.

Timely 699R 704R Acetaminophen Extended-Release Tablets USP, 650 mg

Active ingredient (in each caplet)

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

For Arthritis Pain

temporarily relieves minor aches and pains due to:

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

temporarily reduces fever

For Muscle Aches & Pains

temporarily relieves minor aches and pains due to:

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

temporarily reduces fever

Warnings

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

- more than 6 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.

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

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 using 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:

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

For Arthritis Pain

Do not take more than directed. See overdose warning

adults:

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

under 18 years of age: ask a doctor

For Muscle Aches & Pains

Do not take more than directed. See overdose warning

adults and children 12 years and over:

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

children under 12 years:do not use

Other information

- store between 20-25°C (68-77°F)
- The FDA approved Dissolution methods differ from USP

Inactive ingredients carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin


Questions or comments?

Call **1-877-290-4008**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Relabeled and Repackaged by:
Enovachem PHARMACEUTICALS
Torrance, CA 90501

Relabeled By:
Enovachem PHARMACEUTICALS 379 Van Ness Ave, Suite 1403-1406, Torrance, CA 90501
Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-40
Qty: 400



(01) 0 0376420 91440 2
(17)
(10) 00000000
(21)

Distributed By: Time-Cap Labs, Inc.
Source NDC: 49483-699-40
Description: white to off white;capsule shaped/71
Lot #: 00000000 Exp:
Batch #: 00000000
Drug Status: OTC


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 ER Tablets USP, 650 mg
NDC: 76420-914-40
S/N:
Qty: 400

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-40
S/N:
Qty: 400

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-40
S/N:
Qty: 400

Packaged By:
Enovachem PHARMACEUTICALS 379 Van Ness Ave, Suite 1403-1406, Torrance, CA 90501
Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-60
Qty: 60



(01) 0 0376420 91460 0
(17)
(10) 00000000
(21)

Distributed By: Time-Cap Labs, Inc.
Source NDC: 49483-699-01
Description: white to off white;capsule shaped/71
Lot #: 00000000 Exp:
Batch #: 00000000
Drug Status: OTC


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 ER Tablets USP, 650 mg
NDC: 76420-914-60
S/N:
Qty: 60

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-60
S/N:
Qty: 60

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-60
S/N:
Qty: 60

Relabeled By:
Enovachem PHARMACEUTICALS 379 Van Ness Ave, Suite 1403-1406, Torrance, CA 90501
Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-01
Qty: 100



(01) 0 0376420 91401 3
(17)
(10) 00000000
(21)

Distributed By: Time-Cap Labs, Inc.
Source NDC: 49483-699-01
Description: white to off white;capsule shaped/71
Lot #: 00000000 Exp:
Batch #: 00000000
Drug Status: OTC


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 ER Tablets USP, 650 mg
NDC: 76420-914-01
S/N:
Qty: 100

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-01
S/N:
Qty: 100

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-01
S/N:
Qty: 100

Relabeled By:
Enovachem PHARMACEUTICALS 379 Van Ness Ave, Suite 1403-1406, Torrance, CA 90501
Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-05
Qty: 50



(01) 0 0376420 91405 1
(17)
(10) 00000000
(21)

Distributed By: Time-Cap Labs, Inc.
Source NDC: 49483-699-05
Description: white to off white;capsule shaped/71
Lot #: 00000000 Exp:
Batch #: 00000000
Drug Status: OTC


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 ER Tablets USP, 650 mg
NDC: 76420-914-05
S/N:
Qty: 50

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-05
S/N:
Qty: 50

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-05
S/N:
Qty: 50

Relabeled By:
Enovachem PHARMACEUTICALS 379 Van Ness Ave, Suite 1403-1406, Torrance, CA 90501
Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-26
Qty: 225



(01) 0 0376420 91426 6
(17)
(10) 00000000
(21)

Distributed By: Time-Cap Labs, Inc.
Source NDC: 49483-699-26
Description: white to off white;capsule shaped/71
Lot #: 00000000 Exp:
Batch #: 00000000
Drug Status: OTC


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 ER Tablets USP, 650 mg
NDC: 76420-914-26
S/N:
Qty: 225

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-26
S/N:
Qty: 225

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-26
S/N:
Qty: 225

Relabeled By:
Enovachem PHARMACEUTICALS 379 Van Ness Ave, Suite 1403-1406, Torrance, CA 90501
Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-42
Qty: 24



(01) 0 0376420 91442 6
(17)
(10) 00000000
(21)

Distributed By: Time-Cap Labs, Inc.
Source NDC: 49483-699-42
Description: white to off white;capsule shaped/71
Lot #: 00000000 Exp:
Batch #: 00000000
Drug Status: OTC

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 ER Tablets USP, 650 mg
NDC: 76420-914-42
S/N:
Qty: 24

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-42
S/N:
Qty: 24

Acetaminophen ER Tablets USP, 650 mg
NDC: 76420-914-42
S/N:
Qty: 24

ACETAMINOPHEN

acetaminophen tablet extended release tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76420-914(NDC:49483-699)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	

Product Characteristics

Color	white (White to off white)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-914-40	400 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2025	
2	NDC:76420-914-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2025	
3	NDC:76420-914-05	50 in 1 CARTON	01/27/2025	
3		1 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:76420-914-26	225 in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2025	
5	NDC:76420-914-42	1 in 1 CARTON	01/27/2025	

5		24 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:76420-914-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215486	10/04/2021	

Labeler - Asclemed USA, Inc. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-914) , repack(76420-914)

Revised: 2/2025

Asclemed USA, Inc.