

**GOOD SENSE PAIN RELIEF ARTHRITIS PAIN- acetaminophen tablet, film coated, extended release  
ASCLEMED USA INC.**

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**Perrigo Arthritis Pain Drug Facts**

**Active ingredient (in each caplet)**

Acetaminophen 650 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- 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

**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 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:**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**

- **do not take more than directed (see overdose warning)**

adults	<ul style="list-style-type: none"><li>•take 2 caplets every 8 hours with water</li><li>•swallow whole; do not crush, chew, split or dissolve</li><li>•do not take more than 6 caplets in 24 hours</li><li>•do not use for more than 10 days unless directed by a doctor</li></ul>
under 18 years of age	<ul style="list-style-type: none"><li>•ask a doctor</li></ul>

**Other information**

- store at 20-25°C (68-77°F)
- **do not use if printed foil under cap is broken or missing**
- meets the requirements of USP *Dissolution Test 4*

**Inactive ingredients**

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

**1-800-719-9260**

Enovachem PHARMACEUTICALS

Torrance, CA 90501

## Principal Display Panel

Packaged By: **Enovachem**<sup>®</sup> 375 Van Ness Ave.  
 Suite 1425-1450  
 San Francisco, CA 94101

**Acetaminophen ER Tablets, 650 mg**

NDC: 76420-590-30

Qty: 30

Distributed By: Perrigo

Source NDC: 0113-0544-X


Description: white, oval, 1544

Lot #: 000000000

Exp: 000000000

Drug Status: OTC

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. USE PACKAGE INSERT FOR FULL PRECAUTIONS. KEEP OUT OF REACH OF CHILDREN. © 2013 Perrigo Company, Inc.





(01) 0157420-590-30  
 (17)  
 (10) 000000000  
 (21)

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-560-30  
S/N:  
Qty: 30

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NDC: 76420-560-30  
S/N:  
Qty: 30

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-560-30  
S/N:  
Qty: 30

Relabeled By  
 **Enovochem**  
 PHARMACEUTICALS  
 375 Van Ness Ave.  
 Suite 1403-1406  
 San Francisco, CA 94109  
 Acetaminophen ER Tablets, 650 mg  
 NDC: 76420-590-01  
 Qty: 100  
 Distributed By: Perrigo  
 Source NDC: 0113-0544-78  
 Description: white oval L544  
 Lot #: 000000000  
 Batch #: 000000000  
 Exp: \_\_\_\_\_  
 Drug Status: OTC  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE BACKING INSERT.  
 AFTER 10/1/13, ALL CRYSTAL OTC AND 544-78 (L544) USE CONTROLLED DRUG MARKING

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-01  
S/N:  
Qty: 100

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-01  
S/N:  
Qty: 100

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-01  
S/N:  
Qty: 100

Packaged By: **Enovachem**  
Pharmaceuticals  
3791 Unit Weiss Ave.  
Suite 1420-1430  
Toronto, CA M6P 0E1

**Acetaminophen ER Tablets, 650 mg**  
NDC: 76420-590-60

Qty: 60

Distributed By: **Perrigo**  
Source NDC: 0113-0545-X  
Description: white,oval,L544  
Lot #: 00000000  
Batch #: 00000000  
Exp: \_\_\_\_\_

Drug Status: OTC

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20°C (68°F); USE UNEXP. CONTROLLED ROOM TEMP.

(01) 01676260 59060 6  
(17)  
(10) 000000000  
(21)

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-60  
S/N:  
Qty: 60

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-60  
S/N:  
Qty: 60

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-60  
S/N:  
Qty: 60

Packaged By: **Enovachem**  
 375 Van Ness Ave.  
 Suite 1420-1405  
 Toronto, CA M5T 1A1  
 Acetaminophen ER Tablets, 650 mg  
 NDC: 76420-590-90  
 Qty: 90  
 Distributed By: **Perrigo**  
 Source NDC: 0113-0544-XX  
 Description: white, oval, L544  
 Lot #: 000000000  
 Batch #: 000000000  
 Exp: \_\_\_\_\_  
 Drug Status: OTC  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 (01) 01352620 59090 3  
 (17)  
 (10) 000000000  
 (21)

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-90  
S/N:  
Qty: 90

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-90  
S/N:  
Qty: 90

Acetaminophen ER Tablets, 650 mg  
NDC: 76420-590-90  
S/N:  
Qty: 90

**GOOD SENSE PAIN RELIEF    ARTHRITIS PAIN**

acetaminophen tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76420-590(NDC:0113-0544)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

## Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	L544
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-590-01	1 in 1 CARTON	06/26/2025	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:76420-590-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2025	
3	NDC:76420-590-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2025	
4	NDC:76420-590-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	11/21/2005	

**Labeler** - ASCLEMED USA INC. (059888437)

## Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-590) , repack(76420-590)