

**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release**  
**Medline Industries, LP**

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**643 Acetaminophen**

***Active ingredient (in each caplet)***

Acetaminophen USP, 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 (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 take more than directed (see overdose warning)**

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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>

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## **Other information**

- store at 20 - 25° C (68 - 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

## **Inactive ingredients**

croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

## ***Questions?***

Call toll free **1-800-MEDLINE (633-5463)** Monday-Friday 9AM-5PM CST

## **Manufacturing Information**

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in USA with domestic and foreign materials

[www.medline.com](http://www.medline.com)/[www.curad.com](http://www.curad.com)

1-800-MEDLINE (633-5463)

REF: OTC33350N

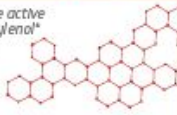
V1 RG22OHM

## **Package Label**



NDC: 53329-643-29

\*Compare to the active ingredient in Tylenol® Arthritis Pain



Arthritis Pain Relief

# Acetaminophen Extended-release Tablets USP, 650 mg

Pain reliever/Fever reducer

- For the temporary relief of minor arthritis pain
- Lasts up to 8 hours

50 Caplets\*

650 mg each

\*Capsule-shaped tablets

## Drug Facts

**Active ingredient (in each caplet)** Acetaminophen USP, 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



DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

TAMPER-EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.



XXXXXXXX

Expiration Date

Lot No.

open here

Non Varnish Area

## Drug Facts (continued)

### 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 non-prescription). If you are not sure whether a drug contains acetaminophen,

## Drug Facts (continued)

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.**

## Drug Facts (continued)

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 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 take for more than 10 days unless directed by a doctor</li> </ul>
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under 18 years of age	ask a doctor
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## Drug Facts (continued)

**Other information**

- Store at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F)

**Inactive ingredients** croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide.

**Questions or comments?** Call toll free 1-800-MEDLINE (633-5463) Monday-Friday 9AM-5PM CST.

[www.medline.com](http://www.medline.com) Packaged in the USA with U.S. and foreign components for: Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA. V1 RG220HM 1-800-MEDLINE

[REF] OTC33350N

Contains No Aspirin

\*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Tylenol® Arthritis Pain.

# ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-643
<b>Route of Administration</b>	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
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<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 (Capsule Shaped)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	cor116
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-643-29	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2018	12/31/2025

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	04/30/2002	12/31/2025

**Labeler** - Medline Industries, LP (025460908)

**Registrant** - Medline Industries, LP (025460908)

## Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(53329-643)