

ACETAMINOPHEN EXTENDED-RELEASE- acetaminophen tablet
Magno-Humphries, Inc.

Acetaminophen Extended-Release Tablets

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 drugs 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

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
-

Other information

- store between 20° to 25°C (68° to 77° F)

Inactive ingredients

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions?

call toll-free 1-800-935-6737

Package Labeling:

Compare to the active ingredient in Tylenol® Arthritis Pain*

Acetaminophen Extended-release Tablets

Pain Reliever/Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

200 CAPLETS • 650 mg each

NDC 54257-573-03

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active ingredient (in each caplet)
Acetaminophen 650 mg.....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
 - 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 drugs 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

PEEL FOR DIRECTIONS

LIFT HERE

67365-200-01-1

Drug Facts (continued)

Stop use and ask a doctor if, cont.

- 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)

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

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions? call toll-free 1-800-335-6737

*This product is not manufactured or distributed by the owner of the registered trademark Tylenol® Arthritis Pain.

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Tigard, OR 97223 U.S.A.
Visit our website:
www.magno-humprins.com

ACETAMINOPHEN EXTENDED-RELEASE			
acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54257-573
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		
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (Off-white)	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	G650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54257-573-02	200 in 1 BOTTLE; Type 0: Not a Combination Product	01/24/2020	01/29/2020
2	NDC:54257-573-03	200 in 1 BOTTLE; Type 0: Not a Combination Product	01/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	01/24/2020	

Labeler - Magno-Humphries, Inc. (063251433)

Revised: 10/2021

Magno-Humphries, Inc.