

MAJOR ACETAMINOPHEN- acetaminophen tablet, film coated, extended release

Major Pharmaceuticals

Major Pharmaceuticals Acetaminophen Extended-Release Tablets, 650 mg 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"> • 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	<ul style="list-style-type: none"> • ask a doctor

Other information

- store at 20-25°C (68-77°F)

- meets the requirements of USP Dissolution Test 2

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

Questions or comments?

1-800-719-9260

Principal Display Panel

MAJOR[®]

Push & Turn Cap

Acetaminophen Extended-Release Tablets, 650 mg

PAIN RELIEVER/FEVER REDUCER

FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

ACTUAL SIZE

CAPLETS

Compare to the active ingredient in Tylenol[®] 8HR Arthritis Pain

400 Caplets* 650 mg. Each

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

*Capsule-Shaped Tablets

NDC 0904-6883-65
Push & Turn Cap

MAJOR[®]


Acetaminophen Extended-Release

Tablets, 650 mg

PAIN RELIEVER/FEVER REDUCER

**FOR THE TEMPORARY RELIEF
OF MINOR ARTHRITIS PAIN** ACTUAL SIZE

Compare to the active ingredient in Tylenol[®] 8HR Arthritis Pain**



CAPLETS

400 Caplets*
650 mg. Each

*Capsule-Shaped Tablets

DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING


Drug Facts	<p>Purpose Active ingredient (in each caplet) Acetaminophen 650 mg. Pain reliever/fever reducer</p> <p>Uses temporarily relieve minor aches and pains due to: backache muscle aches coughs sore throat the common cold headache temporarily reduce fever</p> <p>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 Do not take with any other drug containing acetaminophen Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness rashes rash if a skin reaction occurs, stop use and seek medical help right away.</p> <p>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</p> <p>Ask a doctor before use if you have liver disease</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</p> <p>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 rash or redness occurs redness or swelling is present These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p> <p>Directions 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</p> <p>Other information store at 20-25°C (68-77°F) meets the requirements of USP Dissolution Test 2</p> <p>Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, prepolymethylated starch, stearic acid, titanium dioxide</p> <p>Questions or comments? 1-800-719-9260</p>
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Contains No Aspirin
or Salicylates
U.S. Patent 7,897,772

Gluten Free

Distributed by: MAJOR PHARMACEUTICALS
17177 N. State St.
Livonia, MI 48152

M-05 REV. 08/19 Re-Order No. 701062



*This product is not manufactured or distributed by Johnson & Johnson or Tylenol[®] 8HR Arthritis Pain.

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MAJOR ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6883
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L544
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6883-65	400 in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	03/04/2019	

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2022

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