

ACETAMINOPHEN- acetaminophen tablet
MEIJER DISTRIBUTION INC

Acetaminophen Extended-release tablets USP, 650 mg
Pain Reliever/Fever Reducer
For The Temporary Relief of Minor Arthritis Pain

Contains No Aspirin

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

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

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.

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 ■ 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 20-25°C (68-77°F)

■ **do not use if foil inner seal is broken or missing**


Inactive ingredients

hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP




See New Warning

8HR Arthritis Pain Relief

ACETAMINOPHEN
EXTENDED-RELEASE
TABLETS USP,
650 mg

**Pain Reliever/Fever Reducer
For The Temporary Relief Of Minor
Arthritis Pain
Contains No Aspirin**

400 Caplets**
650 mg each
(**Capsule-Shaped Bi-Layer Tablets)



Actual Size

TO OPEN: PUSH AND TURN CAP
READ THE LABEL

DO NOT USE WITH
OTHER MEDICINES
CONTAINING
ACETAMINOPHEN

NDC 79481-0183-4

COMPARE TO
TYLENOL® 8 HR ARTHRITIS PAIN
ACTIVE INGREDIENT*

Important: Read product information before using.
Do not use if foil liner seal is broken or missing!

Drug Facts

Active Ingredient (in each caplet)
Acetaminophen USP 650 mg Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - backache
 - premenstrual and menstrual cramps
 - the common cold
 - headache
- temporarily reduces fever

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than the recommended dose. Do not take more than 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 redness
- hives
- itching
- swelling
- skin rash

If a skin reaction occurs, stop use and seek medical help right away.

Other warnings:

- do not take with other drugs containing acetaminophen (prescription or over-the-counter). 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 or pharmacist before use if you have liver disease.

Stop use and ask a doctor if

- you experience dizziness, drowsiness, or lightheadedness
- your symptoms do not improve
- your symptoms persist
- your symptoms worsen
- you experience any of the following symptoms:
 - stomach pain
 - nausea
 - vomiting
 - diarrhea
 - constipation
 - dark urine
 - dark stool
 - dark or bloody urine
 - dark or bloody stool
 - dark or bloody sweat
 - dark or bloody tears
 - dark or bloody saliva
 - dark or bloody sputum
 - dark or bloody sweat
 - dark or bloody tears
 - dark or bloody saliva
 - dark or bloody sputum

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

Under 18 years of age

- do not use if foil liner seal is broken or missing

Other information


- store between 20-25° (68-77° F)
- do not use if foil liner seal is broken or missing

Inactive ingredients
hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?
contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

DRY: BY MEIJER DISTRIBUTION, INC.
GROUND BOND, MN 55854
www.meijer.com 800.367.3556


MADE IN INDIA



2000001028
7000000284

Lot Exp.

7 113733 27476 0



*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark, Tylenol®.

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Directions: Read the important information before using.
Keep out of the reach of children.

Drug Facts
Active ingredient(s) (in each caplet): Acetaminophen 650 mg USP

Uses
Temporarily relieves minor aches and pains due to:
Headache
Cough
Chest colds
Flu
Sore throat
Muscle aches
Nerve pain
Stomach aches
Toothaches

Warnings
Do not take if you are already taking acetaminophen. Do not take if you are already taking another medicine that contains acetaminophen. Do not take if you have been told by a doctor that you have liver disease. Do not take if you have been told by a doctor that you have kidney disease. Do not take if you have been told by a doctor that you have a history of alcoholism. Do not take if you have been told by a doctor that you have a history of taking prescription or over-the-counter drugs that contain acetaminophen. Do not take if you are pregnant, trying to get pregnant, or breastfeeding. Do not take if you are taking other medicines that contain acetaminophen. Do not take if you are taking other medicines that contain aspirin or salicylates. Do not take if you are taking other medicines that contain NSAIDs. Do not take if you are taking other medicines that contain MAO inhibitors. Do not take if you are taking other medicines that contain tramadol. Do not take if you are taking other medicines that contain dextropropoxyphene. Do not take if you are taking other medicines that contain hydrocodone. Do not take if you are taking other medicines that contain oxycodone. Do not take if you are taking other medicines that contain morphine. Do not take if you are taking other medicines that contain codeine. Do not take if you are taking other medicines that contain buprenorphine. Do not take if you are taking other medicines that contain fentanyl. Do not take if you are taking other medicines that contain propofol. Do not take if you are taking other medicines that contain etomidate. Do not take if you are taking other medicines that contain midazolam. Do not take if you are taking other medicines that contain benzodiazepines. Do not take if you are taking other medicines that contain barbiturates. Do not take if you are taking other medicines that contain general anesthetics. Do not take if you are taking other medicines that contain skeletal muscle relaxants. Do not take if you are taking other medicines that contain anticholinergics. Do not take if you are taking other medicines that contain antihistamines. Do not take if you are taking other medicines that contain decongestants. Do not take if you are taking other medicines that contain cough suppressants. Do not take if you are taking other medicines that contain expectorants. Do not take if you are taking other medicines that contain antacids. Do not take if you are taking other medicines that contain laxatives. Do not take if you are taking other medicines that contain stool softeners. Do not take if you are taking other medicines that contain urinary acidifiers. Do not take if you are taking other medicines that contain urinary alkalinizers. Do not take if you are taking other medicines that contain diuretics. Do not take if you are taking other medicines that contain electrolyte supplements. Do not take if you are taking other medicines that contain vitamins. Do not take if you are taking other medicines that contain minerals. Do not take if you are taking other medicines that contain herbal products. Do not take if you are taking other medicines that contain dietary supplements. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain acetaminophen. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain aspirin or salicylates. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain NSAIDs. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain MAO inhibitors. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain tramadol. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain dextropropoxyphene. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain hydrocodone. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain oxycodone. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain morphine. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain codeine. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain buprenorphine. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain fentanyl. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain propofol. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain etomidate. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain midazolam. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain benzodiazepines. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain barbiturates. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain general anesthetics. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain skeletal muscle relaxants. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain anticholinergics. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain antihistamines. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain decongestants. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain cough suppressants. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain expectorants. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain antacids. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain laxatives. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain stool softeners. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain urinary acidifiers. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain urinary alkalinizers. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain diuretics. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain electrolyte supplements. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain vitamins. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain minerals. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain herbal products. Do not take if you are taking other medicines that contain prescription or over-the-counter drugs that contain dietary supplements.

Other information
Keep out of the reach of children.
Do not use if the caplet is broken or missing.

Contains No Aspartame

200000004291

700000003293

Drug Facts (continued)

Contains No Aspartame

100 mg each caplet
225 Caplets (11 1/2 boxes)
NDC 0075-0109-01 (11 1/2 boxes)
www.meijer.com

100 mg each caplet
225 Caplets (11 1/2 boxes)
NDC 0075-0109-01 (11 1/2 boxes)
www.meijer.com

meijer.

8HR Arthritis Pain Relief

ACETAMINOPHEN EXTENDED-RELEASE TABLETS USP, 650 mg

Pain Reliever/Fever Reducer
For The Temporary Relief of Minor Arthritis Pain
Contains No Aspartame

meijer.

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100 mg each caplet
225 Caplets (11 1/2 boxes)
NDC 0075-0109-01 (11 1/2 boxes)
www.meijer.com

7 3733 2745 5

LOT

EXP.

meijer. See New Warning
8HR Arthritis Pain Relief COMPARE TO TYLENOL® 8 HR ARTHRITIS PAIN ACTIVE INGREDIENT*
ACETAMINOPHEN EXTENDED-RELEASE TABLETS USP, 650 mg
 Pain Reliever/Fever Reducer For The Temporary Relief Of Minor Arthritis Pain Contains No Aspirin
 150 Caplets** 650 mg each (**Capsule-Shaped Bi-Layer Tablets)
 NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN
 Actual Size

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN
 NDC 79481-0183-5

Important: Read all product information before using.
 Do not use if foil inner seal is broken or missing.

Drug Facts
Active ingredient (in each caplet)
 Acetaminophen USP, 650 mg. Pain reliever/fever reducer

Uses
 temporarily relieves minor aches and pains due to:
 minor pain of arthritis
 muscle aches
 backache
 rheumatoid 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 redness
 hives
 rash
 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.

www.meijer.com
 DIST. BY MEIJER DISTRIBUTION, INC. (CONTINUED ON BACK OF LABEL)
 GRAND RAPIDS, MI 49544
 FD 437128

LOT
 EXP
 200000004289
 700000003292

MADE IN INDIA

simulate a printed label,
 along dotted line.

Inside (adhesive side)

Drug Facts (continued)
 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) (Seek 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)
 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

Other information
 Store between 20-25°C (68-77°F)
 Do not use if foil inner seal is broken or missing

Inactive ingredients
 hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?
 contact 1-877-709-9183 Mon-Fri 8:00 AM-EST to 5:00 PM PST

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79481-0183
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
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY35J)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79481-0183-5	150 in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2023	
2	NDC:79481-0183-2	225 in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2023	
3	NDC:79481-0183-4	400 in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	07/17/2023	

Labeler - MEIJER DISTRIBUTION INC (006959555)

Revised: 12/2023

MEIJER DISTRIBUTION INC