

**ARTHRITIS PAIN- acetaminophen tablet, extended release
MARC GLASSMAN, INC.**

1200A-MAR-2021-0304

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, unless directed by a doctor▪ 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 between 20-25°C (68-77°F)
- retain carton for complete product information and warnings

Inactive ingredients

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose,

polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

NDC 68998-300-03

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

Marc's®

8 Hour

Arthritis Pain

Acetaminophen Extended-Release Tablets, 650mg

For the temporary relief of minor arthritis pain

100 CAPLETS**

**Capsule-Shaped Bi-Layer Tablets

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING



DO NOT USE IF IMPRINTED SEAL
UNDER CAP IS BROKEN OR MISSING

F1200403MAR Pain

This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol 8 HR Arthritis Pain.

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 - the common cold
 - headache
 - toothache
 - menstrual and menstrual cramps
 - temporarily reduces fever

Warnings

Liver warnings: 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

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 or pharmacist before use if you are taking the blood thinning drug warfarin

Drug Facts (continued)

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.

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ask a doctor

under 18 years of age

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Inactive ingredients hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments? 1-844-705-4384

8 Hour
Arthritis Pain
PAIN RELIEVER / FEVER REDUCER



Distributed by:
Marc Classman, Inc.
West 130th Street
Cleveland, OH 44130
Made in India

NDC 68998-300-03

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



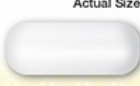
8 Hour
Arthritis Pain

PAIN RELIEVER / FEVER REDUCER

Acetaminophen Extended-Release Tablets, 650mg

For the temporary relief of minor arthritis pain

100 CAPLETS**
**Capsule-Shaped Bi-Layer Tablets



NDC 68998-300-03

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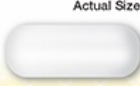
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ARTHRITIS PAIN acetaminophen tablet, extended release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-300
Route of Administration	ORAL		

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 (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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:68998-300-03	1 in 1 CARTON	03/31/2020	08/31/2025
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	03/31/2020	08/31/2025

Labeler - MARC GLASSMAN, INC. (094487477)