## PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated MARC GLASSMAN, INC.

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1170-MAR-2022-0915

**Drug Facts** 

#### Active ingredient (in each gelcap)

Acetaminophen 500 mg

#### **Purpose**

Pain reliever/fever reducer

#### Uses

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

#### **Warnings**

#### Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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 and children 12 years and over	<ul> <li>take 2 gelcaps every 6 hours while symptoms last</li> <li>do not take more than 6 gelcaps in 24 hours, unless directed by a doctor</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	<ul><li>ask a doctor</li></ul>

#### Other information

- store between 20-25°C (68-77°F)
- retain carton for complete product information

#### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, D&C red #33, edible ink, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone,

pregelatinized starch, stearic acid, titanium dioxide

#### PRINCIPAL DISPLAY PANEL

Marc's ®

NDC 68998-070-03

†Compare to the active ingredient in Tylenol® Extra Strength Rapid Release Gels

Extra Strength • For Adults

Pain Relief

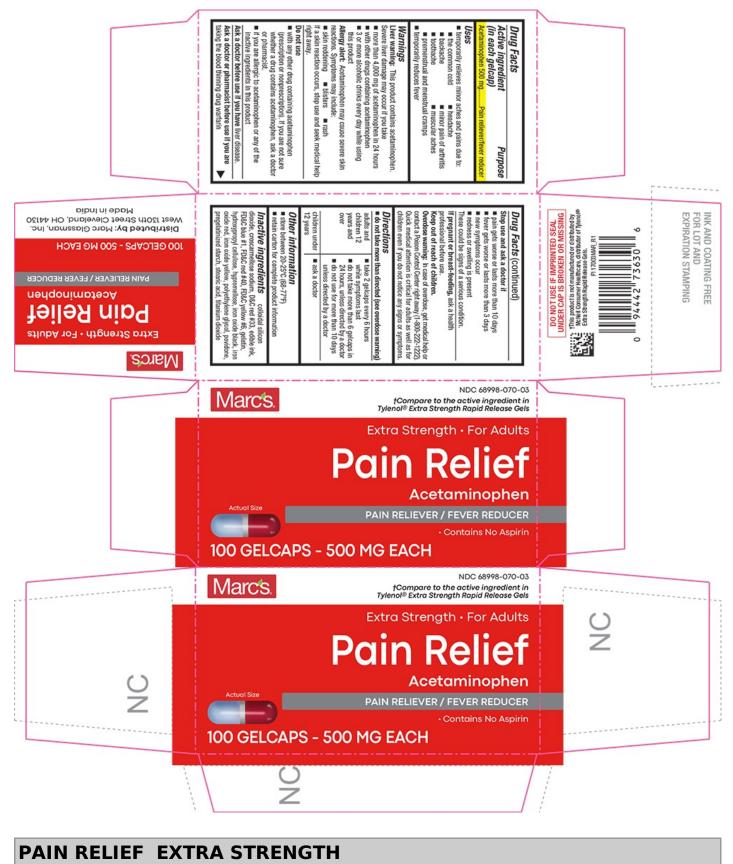
Acetaminophen

PAIN RELIEVER / FEVER REDUCER

• Contains No Aspirin

**Actual Size** 

100 GELCAPS - 500 MG EACH



# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68998-070 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX43802MRT)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	gray (red and light blue ends)	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	G1
Contains			

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:68998- 070-03	1 in 1 CARTON	09/15/2022		
	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
OTC Monograph Drug	M013	09/15/2022	

### Labeler - MARC GLASSMAN, INC. (094487477)

Revised: 10/2024 MARC GLASSMAN, INC.