# PAIN RELIEF- acetaminophen tablet, coated DISCOUNT DRUG MART

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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1098-DDM-2022-1003

**Drug Facts** 

## Active ingredient (in each caplet)

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 caplets every 6 hours while symptoms last</li> <li>swallow whole - do not crush, chew, or dissolve</li> <li>do not take more than 6 caplets 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**

acesulfame potassium, flavor, hypromellose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

### Questions or comments?

1-844-705-4384

#### PRINCIPAL DISPLAY PANEL

DISCOUNT drug mart FOOD FAIR

NDC 53943-298-03

†Compare to the active ingredient in Tylenol® Extra Strength

Extra Strength

Pain Relief

Acetaminophen Caplets, 500 mg

Pain Reliever / Fever Reducer

**Instant Cooling Sensation** 

For Adults

**COOL TASTE CAPLETS** 

**Actual Size** 

100 CAPLETS - 500 MG EACH



## **PAIN RELIEF**

acetaminophen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-298
Route of Administration	ORAL		

# **Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength
	ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients		
	Ingredient Name	Strength

ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ 989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor	MINT	Imprint Code	AAA;1098
Contains			

l	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	<b>1</b> NDC:53943-298-03	1 in 1 CARTON	03/19/2007			
l	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 not final	part343	03/19/2007	

# Labeler - DISCOUNT DRUG MART (047741335)

Revised: 10/2022 DISCOUNT DRUG MART