

ACETAMINOPHEN- acetaminophen capsule, liquid filled
Softgel Healthcare Pvt Ltd

Acetaminophen Capsules USP 500mg (Minis - Red Opaque)

Active ingredient (in each Softgel)

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 warnings:

In case of overdose, get medical help or contact a Poison Control Center right away. 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 style="list-style-type: none">• take 2 capsules every 6 hours while symptoms last• do not take more than 6 capsules in 24 hours, unless directed by a doctor• do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients

FD&C red 40, gelatin, polyethylene glycol 400, purified water, sorbitol sorbitan solution,

titanium dioxide

Bulk Package Label

<u>ACETAMINOPHEN CAPSULES USP 500 MG (MINIS - RED OPAQUE)</u>				IMPRINT	
Each Soft Gelatin Capsule Contains: (Acetaminophen USP 500mg)					
BATCH NO	:	NDC NO	:	35916-0183-2	
MFG DATE	:	GROSS WT	:		
EXP DATE	:	NET WT	:		
QUANTITY	:	SHIPPER NO.	:		
<u>WARNING</u> KEEP OUT OF REACH OF CHILDREN.					
<u>STORAGE</u> STORE BETWEEN 20-25 (68-77 F)					
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.					
MANUFACTURED BY: SOFTGEL HEALTHCARE PVT. LTD., SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM VILLAGE, KANCHEEPURAM, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO:XXXXX			MANUFACTURED FOR		
CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”					

ACETAMINOPHEN			
acetaminophen capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0183
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	500 mg
Inactive Ingredients			
Ingredient Name			Strength
SORBITOL (UNII: 506T60A25R)			

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
GELATIN (UNII: 2G86QN327L)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color	red (Opaque)	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0183-2	3000 in 1 POUCH; Type 0: Not a Combination Product	05/17/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		05/17/2025	

Labeler - Softgel Healthcare Pvt Ltd (675584180)

Revised: 5/2025

Softgel Healthcare Pvt Ltd