

**ACETAMINOPHEN- acetaminophen capsule, liquid filled**  
**Softgel Healthcare Pvt Ltd**

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**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"> <li>• take 2 capsules every 6 hours while symptoms last</li> <li>• do not take more than 6 capsules 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	ask a doctor

**Other information**

- store between 20-25°C (68-77°F)

**Inactive ingredients**

FD&C red 40, gelatin, glycerin, polyethylene glycol 400, polyoxyl 40 hydrogenated castor

oil, povidone K30, purified water, sorbitol sorbitan solution, titanium dioxide

**package label**

<b><u>ACETAMINOPHEN CAPSULES USP 500 MG (MINIS-RED OPAQUE)</u></b>		Imprint
<u>Each Soft Gelatin Capsule Contains:</u> (Acetaminophen USP 500mg)		
BATCH NO :	NDC NO :	35916 - 0183 - 4
MFG DATE :	GROSS WT :	
EXP DATE :	NET WT :	
QUANTITY :	SHIPPER NO. :	
<b><u>WARNING: KEEP OUT OF REACH OF CHILDREN</u></b>		
<b><u>STORAGE</u></b> STORE BETWEEN 20-25°C (68-77°F)		
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.		
<b>MANUFACTURED BY:</b> <b>SOFTGEL HEALTHCARE PVT. LTD.,</b> SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO: XXXX	<b>MANUFACTURED FOR</b>	
<b><u>CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKAGING"</u></b>		

**ACETAMINOPHEN**

acetaminophen capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0183
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	

### Product Characteristics

<b>Color</b>	red (Opaque)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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	
2	NDC:35916-0183-3	2 in 1 BOX	09/24/2025	
2		2000 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:35916-0183-4	2 in 1 BOX	01/13/2026	
3		1500 in 1 BAG; 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	05/17/2025	

**Labeler** - Softgel Healthcare Pvt Ltd (676666501)

Revised: 1/2026

Softgel Healthcare Pvt Ltd