

**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, polyethylene glycol 400, purified water, sorbitol sorbitan solution,

titanium dioxide

## Bulk Package Label

|  |                         |              |
|--|-------------------------|--------------|
| <b><u>ACETAMINOPHEN CAPSULES USP 500 MG (MINIS - RED OPAQUE)</u></b>   |                         | IMPRINT      |
| <u>Each Soft Gelatin Capsule Contains:</u><br>(Acetaminophen USP 500mg)  |                         |              |
| BATCH NO :   | NDC NO :                | 35916-0183-2 |
| MFG DATE :   | GROSS WT :              |              |
| EXP DATE :   | NET WT :                |              |
| QUANTITY :   | SHIPPER NO. :           |              |
| <b>WARNING</b><br>KEEP OUT OF REACH OF CHILDREN.   |                         |              |
| <b>STORAGE</b><br>STORE BETWEEN 20-25 (68-77 F)  |                         |              |
| THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.<br>CONTENTS SHOULD BE APPROVED, REPACKED AND LABELED IN STRICT CONFORMANCE WITH THE FD&C<br>ACT AND REGULATIONS.   |                         |              |
| <b>MANUFACTURED BY:</b><br>SOFTGEL HEALTHCARE PVT. LTD.,<br>SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD,<br>PUDUPAKKAM VILLAGE, KANCHEEPURAM,<br>TAMILNADU 603 103, INDIA (IND)<br>LABELLER CODE: 35916<br>LIC NO:XXXXX | <b>MANUFACTURED FOR</b> |              |
| <b>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</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 |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN     | 500 mg   |

### Inactive Ingredients

| Ingredient Name             | Strength |
|-----------------------------|----------|
| SORBITOL (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>GELATIN</b> (UNII: 2G86QN327L)                 |  |
| <b>WATER</b> (UNII: 059QF0KO0R)                   |  |

### 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           |                    |

### 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