ACETAMINOPHEN - APAP 8 HOUR- acetaminophen tablet, film coated, extended release
Valu Merchandisers Company

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ACETAMINOPHEN Extended-release Tablets

Drug Facts

Active ingredient (in each caplet)
Acetaminophen USP, 650 mg

Purpose
Pain reliever/fever reducer

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

Warnings

Liver warning
This product contains acetaminophen. Severe liver damage may occur if you take
- more than 6 caplets in 24 hours, which is the maximum daily amount
- 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 | take 2 caplets every 8 hours with water  
| | swallow whole; do not crush, chew, split or dissolve  
| | do not take more than 6 caplets in 24 hours  
| | do not use for more than 10 days unless directed by a doctor  
| children under 12 years | do not use  

**Other information**

- see end panel for batch number and expiration date
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

**Inactive ingredients**

croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

**Questions?**

call 1-800-406-7984

PROUDLY DISTRIBUTED BY:
VALU MERCHANDISERS, CO.
5000 KANSAS AVE
KANSAS CITY, KS 66106

**PRINCIPAL DISPLAY PANEL - 650 mg Caplet Bottle Carton**

COMPARE TO THE ACTIVE INGREDIENT OF TYLENOL® 8 HOUR**
Pain Relief
Best Choice®

ACTUAL SIZE

Last up to 8 Hours
Use Only as Directed.

ACETAMINOPHEN
Extended-release Tablets USP, 650 mg
Pain Reliever/Fever Reducer
For Up to 8 Hours Relief of Minor Muscle Aches & Pain
50 CAPLETS*
(*CAPSULE-SHAPED TABLETS)
DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN
# ACETAMINOPHEN - APAP 8 HOUR

acetaminophen tablet, film coated, extended release

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:63941-336</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td></td>
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</table>
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)</td>
<td>ACETAMINOPHEN</td>
<td>650 mg</td>
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</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)</td>
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</tr>
<tr>
<td>HYPRO MELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)</td>
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<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6E0)</td>
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<tr>
<td>MICROCRYSTALLINE CELLULOSE (UNII: OPIR32D61U)</td>
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<tr>
<td>POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)</td>
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<tr>
<td>STARCH, CORN (UNII: O8232NY3SJ)</td>
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<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
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<tr>
<td>SODIUM LAURYL SULFATE (UNII: 368GB5141J)</td>
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<tr>
<td>STEARIC ACID (UNII: 4ELV7Z65AP)</td>
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<tr>
<td>TITANIUM DIOXIDE (UNII: 15FIX9V2JP)</td>
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### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Flavor</th>
<th>Imprint Code</th>
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</thead>
<tbody>
<tr>
<td>white</td>
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<td>OVAL (Capsule Shaped)</td>
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### Packaging

<table>
<thead>
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<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
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<td>NDC:63941-336-50</td>
<td>50 in 1 BOTTLE; Type 0: Not a Combination Product</td>
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### Marketing Information

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<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>ANDA</td>
<td>ANDA076200</td>
<td>04/30/2002</td>
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### Labeler

- Valu Merchandisers Company (868703513)

### Registrant

- Sun Pharmaceutical Industries Inc. (146974886)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Ohm Laboratories Inc.</td>
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<td>184769029</td>
<td>manufacture(63941-336)</td>
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Revised: 12/2019