**ACEPHEN - acetaminophen suppository**  
Cosette Pharmaceuticals, Inc.

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**Acephen™ Acetaminophen Suppositories USP**  
325 mg

*Active Ingredient* (in each rectal suppository)  
Acetaminophen 325 mg

**PURPOSE**  
Pain reliever/fever reducer

**USES**

temporarily  
• reduces fever  
• relieves minor aches, pains, and headache

**WARNINGS**

*For rectal use only*

**Liver Warning:** This product contains acetaminophen. Severe liver damage may occur if  
• a child 6 to 12 years takes more than 5 doses in 24 hours  
• an adult or child 12 years and older takes more than 6 doses in 24 hours, which is the maximum daily amount  
• taken with other drugs containing acetaminophen  
• an adult takes 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**
• in children under 6 years  
• if you are allergic to acetaminophen  
• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use if**
• you have liver disease  
• you are taking the blood thinning drug warfarin

**Stop use and ask a doctor if**
• fever lasts more than 3 days (72 hours), or recurs  
• new symptoms occur  
• pain gets worse or lasts more than 10 days
• redness or swelling is present in the painful area
These may be signs of a serious condition.

*If pregnant or breast-feeding,* ask a health professional before use.
*Keep out of reach of children.* If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.

**DIRECTIONS**

• do not use more than directed
• remove foil wrapper
• insert suppository well up into rectum

<table>
<thead>
<tr>
<th>children under 6 years</th>
<th>do not use</th>
</tr>
</thead>
<tbody>
<tr>
<td>children 6-12 years</td>
<td>1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)</td>
</tr>
<tr>
<td>adults and children 12 years and older</td>
<td>2 suppositories every 4 to 6 hours (maximum of 6 doses)</td>
</tr>
</tbody>
</table>

*Other Information*

• store at room temperature 15°-30°C (59°-86°F)
• do not use if imprinted suppository wrapper is opened or damaged

**INACTIVE INGREDIENTS**
glyceril stearate, hydrogenated vegetable oil, polyethylene glycol 100 stearate, sorbitan monoooleate

**QUESTIONS?**
call 1-800-922-1038

**PRINCIPAL DISPLAY PANEL**
NDC 0713-0164-01
ACEPHEN™ ACETAMINOPHEN SUPPOSITORIES USP 325 mg
Pain Reliever • Fever Reducer
100 Rectal Suppositories
ACEPHEN
acetaminophen suppository

Product Information

<table>
<thead>
<tr>
<th>Item Code (Source)</th>
<th>NDC: 0713-0164</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type</td>
<td>HUMAN OTC DRUG</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>RECTAL</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>325 mg</td>
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</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
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<tbody>
<tr>
<td>GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)</td>
<td></td>
</tr>
<tr>
<td>HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)</td>
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</tr>
<tr>
<td>PEG-100 STEARATE (UNII: YD01N1999R)</td>
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</tr>
<tr>
<td>SORBITAN MONOOLEATE (UNII: 06XEA2VD56)</td>
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</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0713-0164-01</td>
<td>100 in 1 BOX</td>
<td>03/27/1992</td>
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</tr>
<tr>
<td>1</td>
<td></td>
<td>1 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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<tr>
<td>2</td>
<td>NDC:0713-0164-50</td>
<td>50 in 1 BOX</td>
<td>03/27/1992</td>
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<td>2</td>
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<td>1 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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Marketing Information
**Labeler** - Cosette Pharmaceuticals, Inc. (116918230)

**Registrant** - Cosette Pharmaceuticals, Inc. (116918230)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Cosette Pharmaceuticals, Inc.</td>
<td></td>
<td>116918230</td>
<td>analysis(0713-0164) , manufacture(0713-0164) , label(0713-0164) , pack(0713-0164)</td>
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Revised: 8/2019