

Example Drug Facts Label for Acetaminophen 650 mg in a Suppository Dosage Form

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**Drug Facts**

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<b>Active ingredient (in each rectal suppository)</b>	<b>Purposes</b>
Acetaminophen 650 mg.....	Pain reliever/fever reducer

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**Uses** temporarily # reduces fever # relieves minor aches, pains, and headache

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**Warnings**

**For rectal use only**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

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**Do not use** in children under 12 years

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**Stop use and ask a doctor if**

- # fever lasts more than 3 days (72 hours), or recurs
  - # you need to use this product for pain for more than 10 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.
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**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.

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**Directions<sup>1</sup>**

- # **do not use more than directed**
  - # remove foil wrapper
  - # insert suppository well up into rectum
  - # adults and children 12 years and older:
    - # 1 suppository every 4 to 6 hours while symptoms persist
    - # do not exceed 6 suppositories in any 24-hour period
  - # **children under 12 years: do not use**
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**Other information**

- # optional - tamper evident statement

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<sup>1</sup> The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the first three bulleted statements appearing above the top line of the table.

# store at 8-25<sup>0</sup> C (46-77<sup>0</sup> F)<sup>2</sup> or refrigerate

# optional - see [end or side] panel for lot number and expiration date

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***Inactive ingredients*** [list ingredients in alphabetical order]

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***Questions or comments?*** call toll free **1-800-XXX-XXXX**

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NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

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<sup>2</sup> These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their ANDA to support storage up to 27<sup>0</sup> C (80<sup>0</sup> F) may use these temperatures in place of 25<sup>0</sup> C (77<sup>0</sup> F).