

Example Drug Facts Label for Acetaminophen 120 mg in a Suppository Dosage Form

Drug Facts

Active ingredient (in each rectal suppository)	Purposes
Acetaminophen 120 mg.....	Pain reliever/fever reducer

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

Warnings
For rectal use only

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 5 days continuously
Severe or recurrent pain, or high or continued fever may indicate a serious illness.

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 children even if you do not notice any signs or symptoms.

Directions¹
do not use more than directed
remove foil wrapper
insert suppository well up into rectum
children 3 – 6 years:
 # 1 suppository every 4 to 6 hours while symptoms persist
 # do not exceed 6 suppositories in any 24-hour period
children under 3 years: ask a doctor

Other information
optional - tamper evident statement
store at 8-25⁰ C (46-77⁰ F)² or refrigerate
optional - see [end or side] panel for lot number and expiration date

Inactive ingredients [list ingredients in alphabetical order]

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

¹ 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.
² These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their ANDA to support storage up to 27⁰ C (80⁰ F) may use these temperatures in place of 25⁰ C (77⁰ F).

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