Example Drug Facts Label for Acetaminophen 325 mg in a Suppository Dosage Form

Drug Facts

Active ingredient (in each rectal suppository)   ***Purposes***
Acetaminophen 325 mg..….…Pain reliever/fever reducer

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

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.

Do not use in children under 6 years

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.

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

adults and children 12 years and older	2 suppositories every 4 to 6 hours while symptoms persist; do not exceed 12 suppositories in any 24-hour period
children 6 -12 years	1 suppository every 4 to 6 hours while symptoms persist; do not exceed 6 suppositories in any 24-hour period
children under 6 years	**Do not use**

Other information
optional - tamper evident statement
store at 8-25^{0}C (46-77^0 F)[1] or refrigerate

---

[1] These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their ANDA to support storage up to 27^{0}C (80^0 F) may use these temperatures in place of 25^{0}C (77^{0}F).

\# 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**

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