ACETAMINOPHEN FOR CHILDREN- acetaminophen suppository Padagis Israel Pharmaceuticals Ltd

Perrigo Acetaminophen Suppositories USP, 120 mg Drug Facts

Active ingredient (in each rectal suppository)

Acetaminophen 120 mg

Purposes

Pain reliever/fever reducer

Uses

temporarily

- reduces fever
- relieves minor aches, pains, and headache

Warnings

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

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.

For rectal use only

Do not use

- 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

- your child has liver disease
- your child is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- fever lasts more than 3 days (72 hours), or recurs.
- pain lasts more than 5 days or gets worse.
- new symptoms occur.
- redness or swelling is present in the painful area. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) 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

- this product does not contain directions or warnings for adult use
- do not use more than directed
- remove wrapper
- carefully insert suppository well up into the rectum

Dosing Chart			
Age Dose			
under 3 years Do not use unless directed by a doctor			
Use 1 suppository every 4 to 6 hours (maximum of 5 dose in 24 hours)			

Other information

- store at 20-25°C (68-77°F) or in a cool place
- tamper-evident: suppositories are individually wrapped. Do not use if printed wrapper is opened or damaged.

Inactive ingredient

hydrogenated vegetable oil

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to FeverAll® active ingredient

For Children

Acetaminophen Suppositories USP, 120 mg

Pain Reliever/Fever Reducer

Ages 3-6 years

See New Warning

12 RECTAL SUPPOSITORIES, 120 mg EACH



Drug Facts (continued)

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Drug Facts (continued)

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Acetaminophen Suppositories USP, <mark>|</mark>

UDC 45802-732-30



ACETAMINOPHEN FOR CHILDREN

acetaminophen suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-732

Route of Administration RECTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 120 mg

Inactive Ingredients

Ingredient Name	Strength

COTTONSEED OIL (UNII: H3E878020N)

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-732- 33	100 in 1 CARTON	12/14/2010	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:45802-732- 30	12 in 1 CARTON	03/09/2011	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA070607	12/14/2010		

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 11/2021 Padagis Israel Pharmaceuticals Ltd