

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
3 to 6 years	Use 1 suppository every 4 to 6 hours (maximum of 5 doses 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)**Warnings**

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NDC 45802-732-30

**Acetaminophen
Suppositories USP, 120 mg**
Pain Reliever/Fever Reducer

**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: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	120 mg

Inactive Ingredients

Ingredient Name	Strength
COTTONSEED OIL (UNII: H3E878020N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-732-33	100 in 1 CARTON	12/14/2010	09/30/2026
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:45802-732-30	12 in 1 CARTON	03/09/2011	09/30/2026
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	09/30/2026

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 12/2024

Padagis Israel Pharmaceuticals Ltd