

ACETAMINOPHEN PAIN RELIEVER FEVER REDUCER- acetaminophen suppository
Padagis Israel Pharmaceuticals Ltd

Perrigo Acetaminophen Suppositories USP, 650 mg Drug Facts

Active ingredient (in each rectal suppository)

Acetaminophen 650 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

- an adult or child 12 years and older takes more than 6 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
-

an adult takes 3 or more alcoholic drinks every day while using this product

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

- in children under 12 years
- 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

- you have liver disease
- you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- fever lasts more than 3 days (72 hours), or recurs.
- pain gets worse or lasts more than 10 days.
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new symptoms occur.

- redness or swelling is present in the painful area. These may be signs of a serious condition.

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. (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

- **do not use more than directed**

- remove wrapper

- carefully insert suppository well up into the rectum

- adults and children 12 years and older:

- 1 suppository every 4 to 6 hours while symptoms last

- do not exceed 6 suppositories in any 24 hour period

- **children under 12 years: ask a doctor**

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 Adults

Acetaminophen Suppositories USP, 650 mg

Pain Reliever/Fever Reducer

Ages 12 years and older

See New Warning

50 RECTAL SUPPOSITORIES, 650 mg EACH

ACETAMINOPHEN PAIN RELIEVER FEVER REDUCER

acetaminophen suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-730
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
COTTONSEED OIL (UNII: H3E878020N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-730-32	50 in 1 CARTON	11/22/2010	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:45802-730-30	12 in 1 CARTON	10/28/2010	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:45802-730-33	100 in 1 CARTON	10/28/2010	
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:45802-730-00	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/28/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA070608	10/28/2010	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

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