ACETAMINOPHEN FOR CHILDREN- acetaminophen suppository Proficient Rx LP

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	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.

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

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





NDC 63187-373-12

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

Suppositories SN# MASTER

3 63187 37312

Acetaminophen 120mg

#12 Suppositories

Each rectal suppository contains: Acetaminophen 120 mg Pain reliever/ fever reducer

See Box

Ages 3-6 years. For rectal use only

Product ID: RA037312

Dist. By: Perrigo Allegan, MI 49010 Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Acetaminophen 120mg #12 Suppositories SN# MASTER Lot #00000 Exp:00/00/00

Acetaminophen 120mg

#12

Lot #:00000 NDC 63187-373-12

NDC 63187-373-12

Acetaminophen 120mg
#12 Suppositories SN# MASTER
Lot #00000 Exp:00/00/00
NDC 63187-373-12



GTIN: 00363187373122 SN# MASTER Exp. 00/00/00 Lot #:00000

ACETAMINOPHEN FOR CHILDREN

acetaminophen suppository

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63187-373(NDC:45802-732)

Route of Administration RECTAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	ACETAMINOPHEN (UNII: 36209ITI 9D) (ACETAMINOPHEN - UNII: 36209ITI 9D)	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:63187-373- 12	12 in 1 CARTON	09/01/2016	
1		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 - Proficient Rx LP (079196022)

Establishment			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-373), RELABEL(63187-373)

Revised: 9/2022 Proficient Rx LP