ACETAMINOPHEN FOR CHILDREN- acetaminophen suppository NuCare Pharmaceuticals, Inc.

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

NuCare Pharmaceuticals, Inc.

by your physician. Packaged By: NuCare Pharmaceuticals, Inc. Orange, CA 92867 Use only as directed Patient Instructions På llegan, 68071417206*6*000000*000000 MI 49010

NDC: 68071-4172-6 Acetaminophen 120mg #6 Supp.

Each suppository contains Acetaminophen USP, 120mg. Pain reliever/fever reducer Warnings: For rectal use only. 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. 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. Bullet-Shaped Supp. Wrapped in Silver Foil Printed "ACETAMINOPHEN 120mg"

Acetaminophen 120mg Lot: 000000

NDC: 68071-4172-06 MFR NDC: 45802-732-30 Exp.: 00-00

Serial# 00000000002

Acetaminophen 120mg

Lot: 000000 NDC: 68071-4172-06 MFR NDC: 45802-732-30 Exp.: 00-00 Serial# 00000000002

GTIN 00368071417265 Serial# 00000000002 Exp. Date 00-00

LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

Product #: P1235006

WARNING: KEEP OUT OF REACH OF CHILDREN

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STORE AT CONTROLLED TEMPERATURE 68-77°F.

ACETAMINOPHEN FOR CHILDREN

acetaminophen suppository

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:68071-4172(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)

Packaging Marketing Start Marketing End **Item Code Package Description Date Date** 6 in 1 BLISTER PACK; Type 0: Not a Combination NDC:68071-12/04/2017 **Product** 4172-6

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

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment							
Name	Address	ID/FEI	Business Operations				
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-4172)				

Revised: 2/2021 NuCare Pharmaceuticals,Inc.