ACETAMINOPHEN FOR CHILDREN- acetaminophen suppository Acino Products, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Acetaminophen Suppositories - 112 DPL

Drug Facts Active ingredient (in each rectal suppository)

Acetaminophen 120 mg

Purpose

Pain reliever/fever reducer

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 for adults as well as for children even if you do not notice any signs or symptoms.

Uses

- temporarily reduces fever
- temporarily 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

• 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 could be signs of a serious condition.

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)
- tamper evident suppositories are individually wraped.

Do not use if printed wrapper is open or damaged.

Inactive ingredients

Glycerol Monostearate, Hydrogenated Vegetable Oil, Lecithin, Polysorbate 80

Questions or comments?

Call (609-695-4300)

Acetaminophen Suppositories For Children product label

Acion Products

NDC 68784-112-10

*Compare to the active ingredient in Fever All

For Children

Acetaminophen Suppositories USP, 120 mg

Pain reliever/Fever reducer

Age 3-6

See New Warning

10 Rectal Suppositories 120 mg each

Tamper-evident: Suppositories are individually wrapped. Do not use if printed wrapper is open or damaged

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND INFORMATION

Acino Products LLC

9B South Gold Drive

Hamilton, NJ 08691.

MADE IN THE USA

*This product is not manufactured or distributed by Acino Mid Atlantic LLC the distributed of Fever All $\ensuremath{\mathbb{R}}$

Drug Facts (continued)	Drug Facts (continued)	12-10 mg
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Allergy alert: Acetaminophen may cause severe skin reactions.	 It is product does not contain directions or warnings for adult use do not use more than directed remove wrapper 	NDC positories US er reducer 0 mg each
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Keep out of reach of children. If swallowed or in case of overdose, get medical	Questions or comments? Call (609) 695-4300	For Children Acetaminophen Suppositories USP, 120 Pain reliever/Fever reducer 10 Rectal Suppositories 120 mg each
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Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68784-112

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л		MI. 5020511E5	D) (ACETAWII TOTTIEN - OTNI. 502051	1150)	ACETAMIN	OTHEN	120 mg	
In	active Ingredie	nts						
	0		Ingredient Name			S	Strength	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)								
FA	T, HARD (UNII: 8334	4LX7S21)						
			HIN (UNII: H1109Z9J4N)					
H		YBEAN LECITI	. ,					
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Labeler - Acino Products, LLC (019385518)

Registrant - Acino Products, LLC (019385518)

Establishment								
Name	Address	ID/FEI	Business Operations					
Acino Products, LLC		0 19 38 55 18	manufacture(68784-112)					

Revised: 2/2016

Acino Products, LLC