

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 wrapped.

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®

NDC 68784-112-10

For Children
Acetaminophen Suppositories USP, 120 mg
Pain reliever/Fever reducer
10 Rectal Suppositories 120 mg each

Drug Facts (continued)

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.

Aska 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.
Keep out of reach of children. If swallowed or in case of overdose, get medical

Drug Facts (continued)
 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.

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 ingredients Glycerol Monostearate, Hydrogenated Vegetable Oil, Lecithin, Polysorbate 80

Questions or comments? Call (609) 695-4300



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 9 B South Gold Drive
 Hamilton, NJ 08691
 MADE IN USA
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READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

For Children
Acetaminophen Suppositories USP, 120 mg
 Pain reliever/Fever reducer
 Ages 3-6
See New Warning
 10 Rectal Suppositories 120 mg each

2.5in.



Drug Facts

| Active ingredient (in each rectal suppository) | Purpose |
|--|-----------------------------|
| Acetaminophen 120 mg | Pain reliever/fever reducer |

Uses
 ■ temporarily reduces fever ■ temporarily relieves minor aches, pains and headache

ACETAMINOPHEN FOR CHILDREN

acetaminophen suppository

Product Information

| | | | |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68784-112 |
|--------------|----------------|--------------------|---------------|

| | | | | |
|--|--|--|-----------------------------|---------------------------|
| 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 | | |
| | GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | | | |
| | FAT, HARD (UNII: 8334LX7S21) | | | |
| | HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N) | | | |
| | POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:68784-112-10 | 10 in 1 BOX; Type 0: Not a Combination Product | 12/29/2015 | |
| 2 | NDC:68784-112-50 | 50 in 1 BOX; Type 0: Not a Combination Product | 12/29/2015 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part343 | 12/29/2015 | | |

Labeler - Acino Products, LLC (019385518)

Registrant - Acino Products, LLC (019385518)

| | | | |
|----------------------|----------------|---------------|----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Acino Products, LLC | | 019385518 | manufacture(68784-112) |