

**ACETAMINOPHEN FOR ADULTS- 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.*

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**Acetaminophen Suppositories - 113 DPL**

**Drug facts**

**Active ingredient (in each suppository)**

Acetaminophen 650 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

- 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**

- 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**

- if you have liver disease
- if 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 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**

- 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

**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 open or damaged.

**Inactive ingredients**

Glycerol Monostearate, Hydrogenated Vegetable Oil, Lecithin, Polysorbate 80

**Questions or comments?**

Call (609-695-4300)

**Acetaminophen Suppositories For Adults product label****Acino Products**

**NDC 68784-113-10**

\*Compare to the active ingredient in Fever All

**For Adults****Acetaminophen Suppositories USP, 650 mg**

Pain reliever/Fever reducer

Ages 12 and over

**See New Warning**

10 Rectal Suppositories 650 mg each

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

**Drug Facts**  
**Active ingredient (in each rectal suppository)** Acetaminophen 650 mg  
**Purpose** Pain reliever/fever reducer  
**Uses** ■ Temporarily reduces fever ■ Temporarily relieves minor aches, pains and headache



NDC 68784-113-10  
 \*Compare to the active ingredient in Fever All

2.5in.

**For Adults**  
**Acetaminophen Suppositories USP, 650 mg**  
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\*This product is not manufactured or distributed by Actavis Mid Atlantic LLC the distributor of FeverAll®

For Adults  
**Acetaminophen Suppositories USP, 650 mg**  
**Pain reliever/Fever reducer**  
 10 Rectal Suppositories 650 mg each  
 NDC 68784-113-10

<p><b>Drug Facts (continued)</b>  <b>Keep out of reach of children.</b> 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.  <b>Directions</b>      ■ 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  <b>Other information</b>      ■ 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.  <b>Inactive ingredients</b> Glycerol Monostearate, Hydrogenated Vegetable Oil, Lecithin, Polysorbate 80  <b>Questions or comments?</b> Call (609) 695-4300</p>	<p><b>Drug Facts (continued)</b>  <b>Warnings</b>      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  <b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash      If a skin reaction occurs, stop use and seek medical help right away.  <b>For rectal use only</b>      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.  <b>Ask a doctor before use if</b>      ■ if you have liver disease      ■ if you are taking the blood thinning drug warfarin  <b>Stop use and ask a doctor if</b>      ■ fever lasts more than 3 days (2 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.</p>
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<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68784-113
<b>Route of Administration</b>	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
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:68784-113-10	10 in 1 BOX; Type 0: Not a Combination Product	12/29/2015	
2	NDC:68784-113-50	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(68784-113)