

**FEVERALL INFANTS- acetaminophen suppository**  
**Actavis Mid Atlantic LLC**

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**FeverAll® (Acetaminophen Suppositories) INFANTS**

**ACTIVE INGREDIENT**

Acetaminophen, USP 80 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 4 doses in 24 hours, which is the maximum daily amount for ages 6 to 11 months
- more than 5 doses in 24 hours, which is the maximum daily amount for ages 12 to 36 months
- 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**

- the child has liver disease.
- the 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 3 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. 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

<b>Dosing Chart</b>	
<b>Age</b>	<b>Dose</b>
under 6 months	Do not use unless directed by a doctor
6 to 11 months	Use 1 suppository every 6 hours (maximum of 4 doses in 24 hours)
12 to 36 months	Use 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)

## **Other information**

- store at 2°-27°C (35°-80°F)
- do not use if imprinted suppository wrapper is opened or damaged

## **INACTIVE INGREDIENTS**

Glycerol monostearate, hydrogenated vegetable oil, polyoxyethylene stearate, polysorbate 80

## **QUESTIONS**

1-800-432-8534 between 9 am and 4 pm EST, Monday – Friday.

## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**Infants'**

**Ages 6-36 months**

**80 mg**

NDC 0472-1200-06

**FeverAll®**

Acetaminophen Suppositories

Pain reliever/fever reducer

6 Rectal Suppositories

80 mg each

12 of 5  
PP#



Dosing Chart	
Age	Dose
6 to 11 months	Use 1 suppository every 6 hours (maximum of 4 doses in 24 hours)
12 to 36 months	Use 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)

Do not use unless directed by a doctor under 6 months

• carefully insert suppository well up into the rectum

• remove wrapper

• do not use more than directed

**Directions** • this product does not contain directions or warnings for adult use

**Keep out of reach of children.** If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.

**Warnings:** This product contains acetaminophen. Severe liver damage may occur if your child takes more than 4 doses in 24 hours, which is the maximum daily amount for ages 6 to 11 months more than 5 doses in 24 hours, which is the maximum daily amount for ages 12 to 36 months

**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.

**Ask a doctor before use if**

• the child has liver disease.

• the child is taking the blood thinning drug warfarin.

**Drug Facts (continued)**

**Warnings:** This product contains acetaminophen. Severe liver damage may occur if your child takes more than 4 doses in 24 hours, which is the maximum daily amount for ages 6 to 11 months more than 5 doses in 24 hours, which is the maximum daily amount for ages 12 to 36 months

**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**

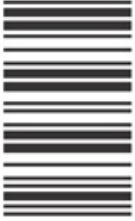
• if you are allergic to acetaminophen

• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use if**

• the child has liver disease.

• the child is taking the blood thinning drug warfarin.



**Drug Facts**

**Active ingredient (in each rectal suppository)** Acetaminophen, USP 80 mg

**Purposes** Pain reliever/fever reducer

**Uses** temporarily

- reduces fever
- relieves minor aches, pains, and headache



NDC 0472-1200-06

**Infants'**

**Ages 6-36 months**

**80 mg**



**FeverAll**

**Acetaminophen Suppositories**  
Pain reliever/fever reducer

**6 Rectal Suppositories**

**80 mg each**



Dist. by Actavis Mid Atlantic LLC, Lincoln, NC 28092 USA Made in USA  
**Tamper-evident: Suppositories are individually wrapped. Do not use if imprinted wrapper is opened or damaged.**

**FeverAll**  
Acetaminophen  
Suppositories  
Pain reliever/fever reducer

**Drug Facts (continued)**

**Other information** • store at 2°-27°C (35°-80°F)

• do not use if imprinted suppository wrapper is opened or damaged

**Inactive ingredients** glycerol monostearate, hydrogenated vegetable oil, polyoxyethylene stearate, polysorbate 80

**Questions?** 1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

12000813M1 VC101916

## FEVERALL INFANTS

acetaminophen suppository

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0472-1200
<b>Route of Administration</b>	RECTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg

### Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	
PEG-100 STEARATE (UNII: YD01N1999R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0472-1200-06	6 in 1 BOX		
2	NDC:0472-1200-50	50 in 1 BOX		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018337	04/01/1980	

**Labeler** - Actavis Mid Atlantic LLC (809515898)

### Establishment

Name	Address	ID/FEI	Business Operations
Actavis Mid Atlantic LLC		809515898	ANALYSIS(0472-1200) , LABEL(0472-1200) , MANUFACTURE(0472-1200) , PACK(0472-1200)