FEVERALL INFANTS- acetaminophen suppository
Taro Pharmaceuticals U.S.A. Inc.

Feverall®
Infants'

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

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

Dosing Chart

Age	**Dose**
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?

call 1-866-923-4914

Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 6 Suppository Blister Pack Carton

NDC 51672-2114-2

RECTAL
SUPPOSITORY*

*actual size

Doctor Recommended

Pain Reliever/Fever Reducer

- No Parabens or Any Other Preservatives

- No Artificial Colors

INFANTS'
ages 6-36 months

FeverAll®

ACETAMINOPHEN SUPPOSITORIES

Pain Reliever/Fever Reducer

6
Rectal
Suppositories

80
mg
each

NDC 51672-2114-2

RECTAL SUPPOSITORY*

*actual size

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INFANTS'
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ACETAMINOPHEN SUPPOSITORIES

Pain Reliever/Fever Reducer

INFANTS'
ages 6-36 months

FeverAll®

ACETAMINOPHEN SUPPOSITORIES

Pain Reliever/Fever Reducer

6 Rectal Suppositories | **80 mg each**

N 3 51672 21142 4

Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532 Made in USA
GW 7303 Rev. 07/2019

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

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.

12 to 50 months	use 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)

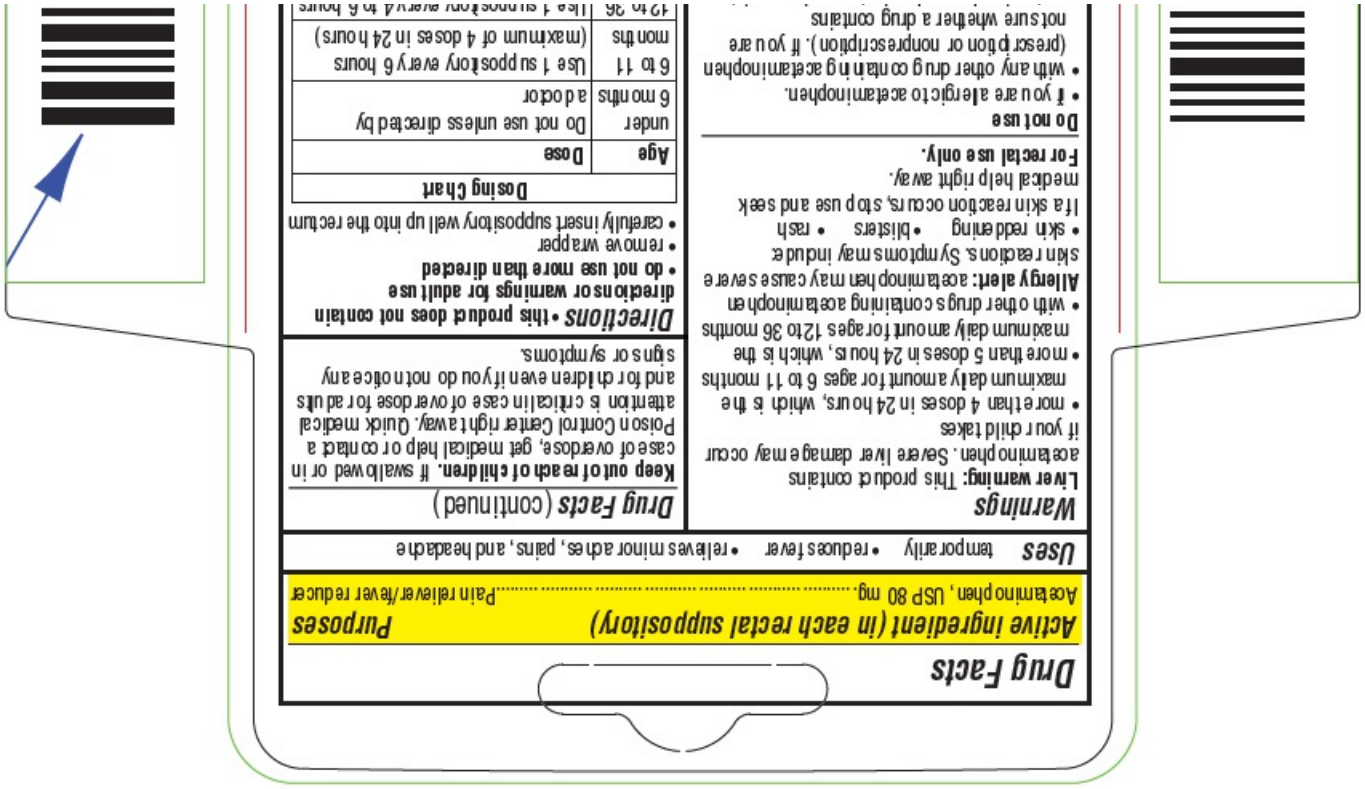
Other information

- 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 sterarate, polysorbate 80

Questions? call 1-866-923-4914



FEVERALL INFANTS

acetaminophen suppository

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2114
Route of Administration	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)	
hydrogenated palm kernel oil (UNII: FM8D1RE2VP)	
PEG-100 stearate (UNII: YD01N1999R)	
polysorbate 80 (UNII: 6OZP39ZG8H)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51672-2114-2	6 in 1 CARTON	12/12/2013	
1	NDC:51672-2114-0	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51672-2114-4	50 in 1 CARTON	12/12/2013	

2	NDC:51672-2114-0	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018337	12/12/2013	

Labeler - Taro Pharmaceuticals U.S.A. Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
G&W NC Laboratories, Inc.		079419931	MANUFACTURE(51672-2114)

Revised: 7/2019 Taro Pharmaceuticals U.S.A. Inc.