

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

Feverall®
Adults

Drug Facts

Active ingredient (in each rectal suppository)

Acetaminophen, USP 650 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

- 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

- in children under 12 years.
- 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

- you have liver disease.
- 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 gets worse or lasts more than 10 days.
- new symptoms occur.
- redness or swelling is present in the painful area.

These may be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before 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.

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
- **children under 12 years: ask a doctor**

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

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 50 Suppository Carton

ADULTS'

ages 12 years & older

FeverAll®

ACETAMINOPHEN SUPPOSITORIES

Pain Reliever/Fever Reducer

NOT FOR RETAIL SALE

NDC 51672-2117-4

RECTAL

SUPPOSITORY*

***actual size**

Doctor Recommended

**50
Rectal
Suppositories**

**650
mg
each**

Questions? call 1-866-923-4914

Inactive ingredients
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Drug Facts (continued)

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• fever lasts more than 3 days (72 hours), or recurs.
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• new symptoms occur.
• redness or swelling is present in the painful area.
These may be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before 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.

Drug Facts (continued)

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Drug Facts

Active ingredient (in each rectal suppository)
Acetaminophen, USP 650 mg.....Pain reliever/fever reducer

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

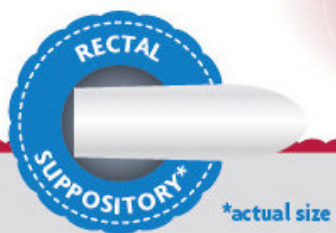
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NDC 51672-2117-4

ADULTS'
ages 12 years & older

FeverAll®
ACETAMINOPHEN SUPPOSITORIES

Pain Reliever/Fever Reducer



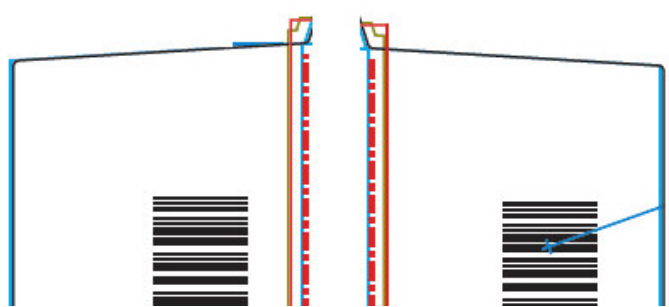
Doctor Recommended

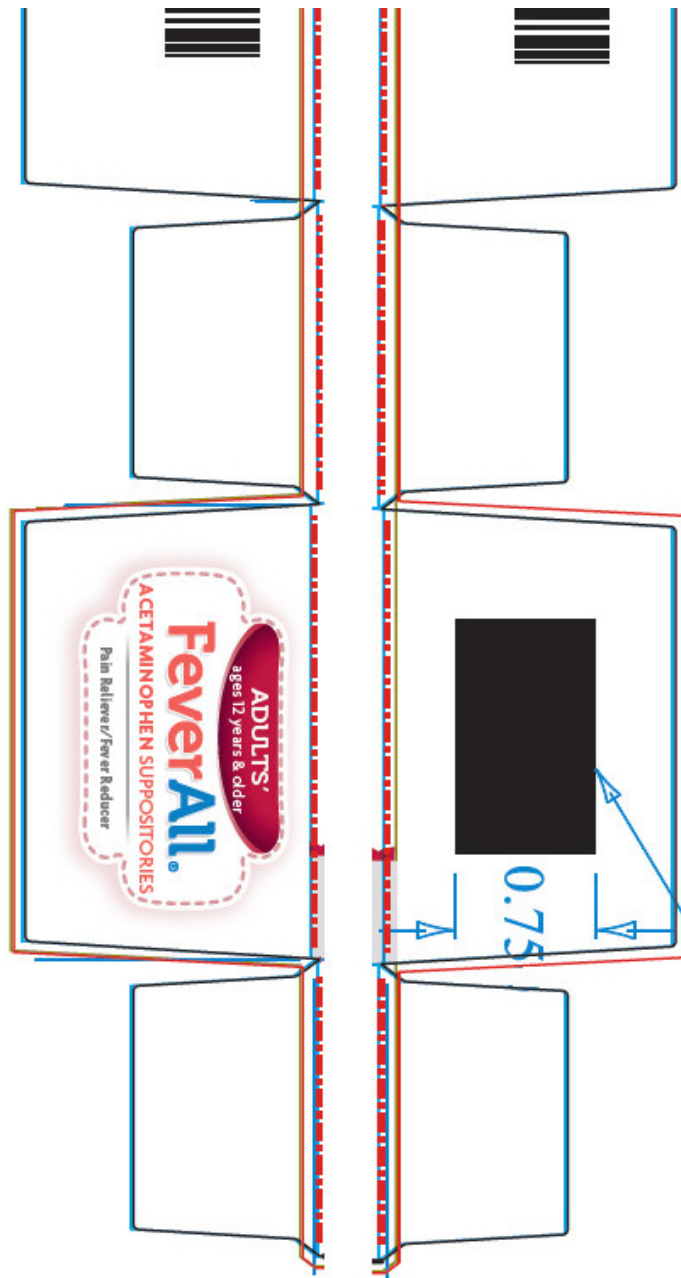
50 Rectal Suppositories

650 mg each

Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
Made in USA
TARO is a registered trademark of
Taro Pharmaceuticals U.S.A., Inc. GW 710016

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





FEVERALL ADULTS

acetaminophen suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2117
Route of Administration	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)	
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:51672-2117-4	50 in 1 CARTON	12/12/2013	
1	NDC:51672-2117-0	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(51672-2117)

Revised: 5/2016

Taro Pharmaceuticals U.S.A. Inc.