

**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release
Fred's Inc.**

Drug Facts

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen USP, 650 mg

PURPOSE

Pain reliever/fever reducer

USES

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - headache
 - toothache
 - the common cold
 - premenstrual and menstrual cramps

- temporarily reduces fever

WARNINGS

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have

Liver disease.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children.

Overdose warning: 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.

DIRECTIONS

- **do not take more than directed (see overdose warning)**

adults	<ul style="list-style-type: none">▪ take 2 caplets every 8 hours with water▪ swallow whole - do not crush, chew, split or dissolve▪ do not take more than 6 caplets in 24 hours▪ do not use for more than 10 days unless directed by a doctor
under 18 years of age	<ul style="list-style-type: none">▪ ask a doctor

OTHER INFORMATION

- store at 20 - 25° C (68 - 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

INACTIVE INGREDIENTS

Croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

QUESTIONS?

Call **1-800-406-7984**

PRINCIPAL DISPLAY PANEL

fred's®

Use only as directed.

See New Warnings Information

LASTS UP TO 8 HOURS

Arthritis Pain Relief

Acetaminophen Extended-Release Tablets, USP 650 mg

Pain Reliever/Fever Reducer

For The Temporary Relief of Minor Arthritis Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

50 CAPLETS*650 mg EACH (*capsule-shaped tablets)

Compare To Active Ingredient of Tylenol® Arthritis Pain†

DISTRIBUTED BY: fred's, Inc.

5095092/R0512

Non Varnish Area

Batch No. 0184579112256618

Expiration Date: _____

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

fred's

Use only as directed.
See New Warnings Information
LASTS UP TO 8 HOURS

Shown at Actual Size

fred's LAB TESTED
We tested for quality and made the difference.

Compare To Active Ingredient of Tylenol® Arthritis Pain

Arthritis Pain Relief
Acetaminophen
Extended-Release Tablets, USP 650 mg
Pain Reliever/Fever Reducer
For The Temporary Relief of Minor Arthritis Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

50 CAPLETS* 650 mg EACH (*capsule-shaped tablets)

fred's Arthritis Pain Relief Acetaminophen LASTS UP TO 8 HOURS

Drug Facts (continued)

Other information

- store at 20° - 25° C (68° - 77° F). Avoid excessive heat, 40° C (104° F).
- see end panel for batch number and expiration date.

Inactive ingredients

croscarmellose sodium, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

Questions? call 1-800-406-7984

Contains No Aspirin

Keep the carton. It contains important information. This product is not manufactured or distributed by McNeil Consumer Healthcare, Inc. The owner of the registered trademark Tylenol® is The Tylenol Company. R0512

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD., MEMPHIS, TN 38118
www.fredsinc.com

fred's Promise
Not Happy With This Product?
Just Bring It Back For a Refund!

Drug Facts (continued)

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Overdose warning: 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.

Directions

- do not take more than directed (see overdose warning)

adults

- take 2 caplets every 8 hours with water
- swallow whole – do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor
- ask a doctor

under 18 years of age

Drug Facts

Active ingredient (in each caplet)
Acetaminophen USP, 650 mg

Purpose
Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - headache
 - toothache
 - the common cold
 - menstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have liver disease.
Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-333
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (Capsule Shaped)	Size	19mm
Flavor		Imprint Code	cor116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-333-50	50 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	04/30/2004	

Labeler - Fred's Inc. (005866116)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Revised: 1/2013

Fred's Inc.