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	▪ 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	▪ 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.

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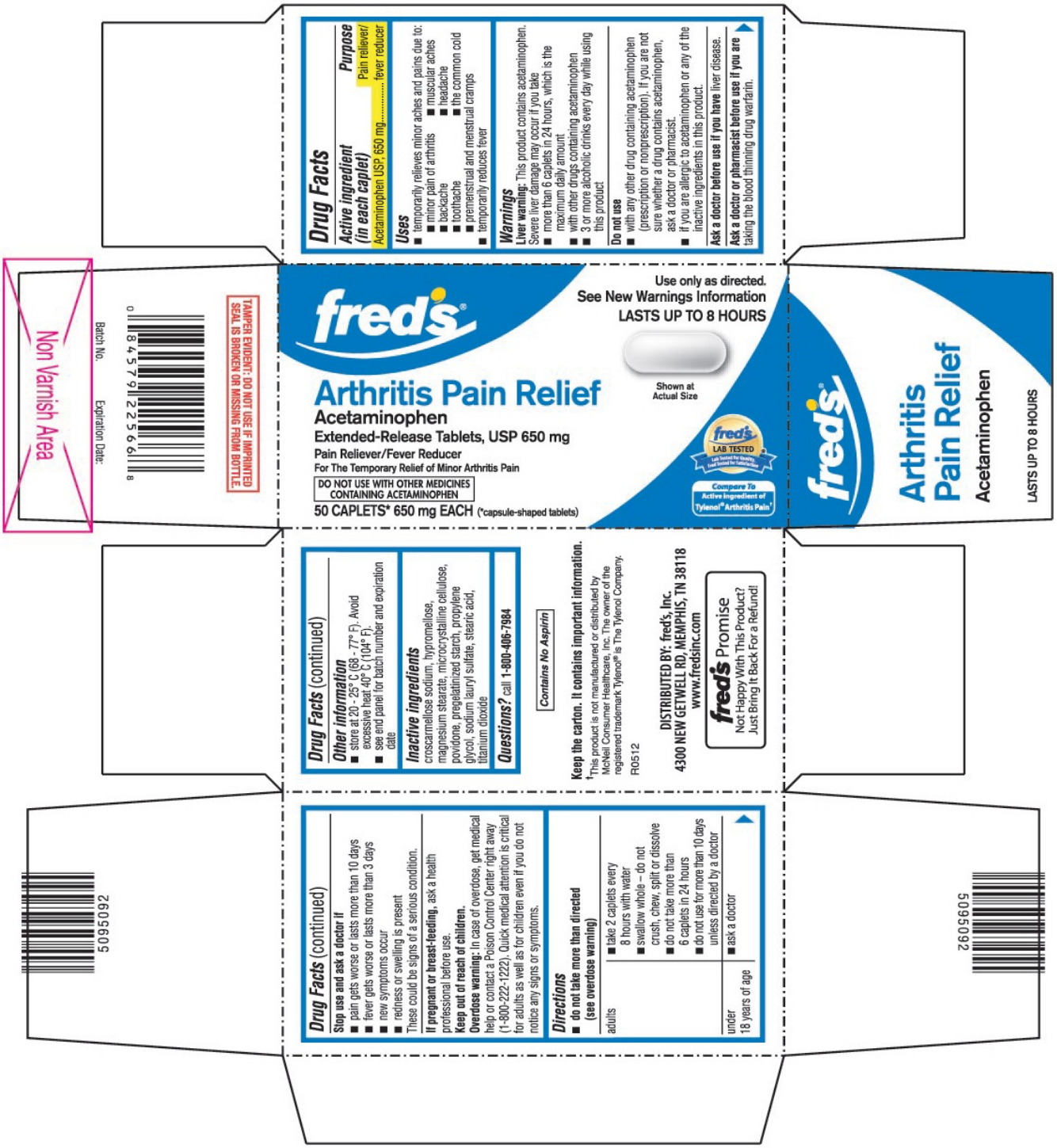

ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM	
HYPROMELLOSES	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONE	
STARCH, PREGELATINIZED CORN	
PROPYLENE GLYCOL	
SODIUM LAURYL SULFATE	
STEARIC ACID	
TITANIUM DIOXIDE	

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

Ohm Laboratories Inc.		184769029	manufacture(55315-333)