PREMIER VALUE ARTHRITIS PAIN RELIEVER- acetaminophen tablet, extended release Premier Value

Drug Facts

ACTIVE INGREDIENT (IN EACH GELTAB)

Acetaminophen USP, 650 mg

PURPOSE

Pain reliever/fever reducer

USES

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - backache
 - headache
 - toothache
 - the common cold
 - minor pain of arthritis
 - 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 geltabs 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 have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.
- 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

• the tablet got stuck in your throat

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 geltabs every 8 hours. Swallow only one geltab at a time. take a sip of water before swallowing each geltab and wash each geltab down with water (up to a full 8 oz. glass). swallow whole - do not crush, chew, split or dissolve do not take more than 6 geltabs 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 high humidity.
- 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, gelatin, glycerin, hypromellose, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, starch, titanium dioxide

QUESTIONS?

Call 1-800-406-7984

PRINCIPAL DISPLAY PANEL

Premier Value®

NDC 68016-340-08

Use only as directed.

See New Warnings Information

EASY TO OPEN BOTTLE

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

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

80 GELTABS* 650 mg EACH

(*Gelatin-Coated Tablets)

COMPARE TO THE ACTIVE INGREDIENT OF TYLENOL $^{\mathbb{R}}$ ARTHRITIS PAIN †

DISTRIBUTED BY CHAIN DRUG CONSORTIUM

5095711/0512



PREMIER VALUE ARTHRITIS PAIN RELIEVER

acetaminophen tablet, extended release

Product Information	n
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Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:68016-340

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (ACETAMINO PHEN)	A C E T A MINO PHE N	650 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM		
GELATIN		
GLYCERIN		
HYPROMELLOSES		
FERROSOFERRIC OXIDE		
FERRIC OXIDE YELLOW		
MAGNESIUM STEARATE		
CELLULOSE, MICRO CRYSTALLINE		
POLYETHYLENE GLYCOLS		
PO VIDO NE		
STARCH, PREGELATINIZED CORN		
PROPYLENE GLYCOL		
STARCH, CORN		
SO DIUM LAURYL SULFATE		
TITANIUM DIO XIDE		

Product Characteristics			
Color	white (White to Yellow)	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	350
Contains			

1	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-340-08	80 in 1 BOTTLE		
2	NDC:68016-340-40	40 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078569	12/21/2012	

Labeler - Premier Value (101668460)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Limited		184769029	manufacture(68016-340)	

Revised: 7/2012 Premier Value