ACETAMINOPHEN- acetaminophen tablet, extended release
Walgreen Company

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. Sever 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

Well at Walgreens

NDC 0363-0340-20

Arthritis Pain Reliever

Acetaminophen Extended-Release Tablets, USP 650 mg

Pain Reliever/Fever Reducer

20 GELTABS

650 mg EACH

Gelatin-Coated tablets

Compare to Tylenol® Arthritis Pain active ingredient‡‡

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

USE ONLY AS DIRECTED

SEE NEW WARNINGS INFORMATION

DISTRIBUTED BY: WALGREEN CO.

5095713/REV0712

ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:0363-0340
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	
GELATIN	
GLYCERIN	
HYPROMELLOSES	
FERROSOFERRIC OXIDE	
FERRIC OXIDE YELLOW	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
POVIDONE	
STARCH, PREGELATINIZED CORN	
PROPYLENE GLYCOL	
SODIUM LAURYL SULFATE	
STARCH, CORN	
TITANIUM DIOXIDE	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0340-20	20 in 1 BOTTLE		
2	NDC:0363-0340-80	80 in 1 BOTTLE		

Marketing Information

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

Labeler - Walgreen Company (008965063)

Registrant - Ranbaxy Pharmaceuticals Inc. (947890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(0363-0340)

Revised: 1/2013 Walgreen Company