

ACETAMINOPHEN- acetaminophen tablet, extended release
CVS Pharmacy

Acetaminophen

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:
 - minor pain of arthritis
 - muscular aches
 - backache
 - premenstrual and menstrual cramps
 - the common cold
 - headache
 - toothache
- 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

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.

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	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ ask a doctor

Other information

- store at 20 - 25° C (68 - 77° F). Avoid high humidity.
- **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 (corn), titanium dioxide

Questions?

call **1-800-406-7984**

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 650 mg Tablet Bottle Label

CVS
HEALTH™

Compare to the active ingredient
in Tylenol® 8HR Arthritis Pain*

Geltabs†

8HR Arthritis
Pain Relief

ACETAMINOPHEN
EXTENDED-RELEASE TABLETS, USP 650 mg

DO NOT USE WITH OTHER
MEDICINES CONTAINING
ACETAMINOPHEN

THIS PACKAGE IS FOR
HOUSEHOLDS WITHOUT
YOUNG CHILDREN

Pain reliever; Fever reducer

- For the temporary relief
of minor arthritis pain
- Lasts up to 8 hours

Use only as directed.

80 GELTABS†
†GELATIN-COATED TABLETS

Actual Size



Compare to the active ingredient in Tylenol® 8HR Arthritis Pain*

Geltabs†

8HR Arthritis Pain Relief

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RO819

5199028



Expiration Date:

Batch No.

open here
Non Varnish Area

#903478



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Drug Facts (continued)

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Drug Facts (continued)

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| | 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 |

Drug Facts (continued)

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ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-930
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)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:69842-930-80	80 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2012	

Marketing Information

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

Labeler - CVS Pharmacy (062312574)**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(69842-930)

Revised: 8/2019

CVS Pharmacy