

EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet, film coated
PuraCap Pharmaceutical LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Extra Strength Acetaminophen Tablets

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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 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 and children 12 years and over	<ul style="list-style-type: none">▪ take 2 caplets every 6 hours while symptoms last▪ do not take more than 6 caplets in 24 hours, unless directed by a doctor▪ do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information

- Store the product at controlled room temperature 15°-30°C (59°-86°F).
- Protect from light, moisture and freezing.

Inactive ingredients

hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl pyrrolidone, pregelatinized starch, stearic acid powder, talc, titanium dioxide

Questions or comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

CVS Extra Strength Acetaminophen Tablets, 500 mg

NDC 51013-320-54



Compare to active ingredient
in Tylenol® Extra Strength*

On-the-go Packettes

NDC 69842-390-54

EXTRA STRENGTH

Acetaminophen

Tablets, 500 mg

Pain reliever; Fever reducer

Convenient on-the-go
packettes

Aspirin free



Tear Open
to Dispense

Package Contains Fifteen Packettes

Actual Size

Distributed by: **CVS Pharmacy, Inc.**
One CVS Drive, Woonsocket, RI 02895
© 2018 CVS/pharmacy
CVS.com® 1-800-SHOP CVS

CVS31-00

Made in India
V-31204



#222649



0 50428 59552 7



Actual Product Size
on Side Panel



Actual Size

Lot No.:

Exp. Date:

COATING
FREE AREA

30 TABLETS
15 PACKETTES (2 TABLETS PER PACKETTE)

**Important: Read all product information before using.
Keep the box for important information.**

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Acetaminophen 500 mg.....	Pain reliever/fever reducer

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Drug Facts (continued)

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***This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® Extra Strength.**

DO NOT USE IF PACKETTE IS TORN OR DAMAGED



Distributed by: **CVS Pharmacy, Inc.**
 One CVS Drive, Woonsocket, RI 02895
 1-800-SHOP CVS Made In India

EXTRA STRENGTH

Acetaminophen

Tablets, 500 mg

Pain reliever; Fever reducer

**DO NOT USE IF
POUCH IS OPENED**

2 CAPLETS

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CVSF30-00

Drug Facts (continued)

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CVSB30-00

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CVSB30-00

EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-320
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	500 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6B0)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	B;H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-320-54	15 in 1 CARTON	11/09/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	11/09/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		9 15664486	manufacture(510 13-320)

Revised: 11/2017

PuraCap Pharmaceutical LLC