

EXTRA STRENGTH PAIN RELIEF- acetaminophen capsule, liquid filled
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 Pain Relief

Drug Facts

Active ingredient (in each softgel)

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 softgels every 6 hours while symptoms last• do not take more than 6 softgels 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 at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special and white edible ink

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

DISCOUNT drug mart

Extra Strength Pain Relief

Acetaminophen 500 mg 80 SOFTGELS

NDC 51013-182-26

*Compare to the active ingredient in **TYLENOL® Extra Strength**

SEE NEW WARNINGS INFORMATION

NDC 51013-182-26



Extra Strength Pain Relief

Acetaminophen 500 mg

PAIN RELIEVER/FEVER REDUCER

**Compare to the active ingredient in TYLENOL® Extra Strength*



80 SOFTGELS

DO NOT USE IF IMPRINTED SAFETY SEAL UNDERCAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each softgel): Acetaminophen 500 mg **Pain reliever/fever reducer**

Uses

- Temporarily relieves minor aches and pains due to:
 - 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 4,000 mg of acetaminophen in 24 hours
 - with other drugs containing acetaminophen
 - 3 or more alcoholic drinks a day while using this product
- Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:
 - skin redness
 - blistering
 - itching
 - swelling
 - skin rash

Do not use

- if you have had a severe allergic reaction to acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, or if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have the following conditions:

- kidney disease
- liver disease
- if you are taking the blood thinning drug warfarin

Drug Facts (continued under label)

DISTRIBUTED BY DISCOUNT DRUG MART-FOOD FAIR
MEDINA, OHIO 44256
www.discount-drugmart.com

SATISFACTION GUARANTEED
IF UNSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE FOR REFUND. RETURNED PORTION MUST BE UNOPENED AND UNMIXED. FOR DISSATISFACTION, NAME, ADDRESS AND PHONE NUMBER OF DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark TYLENOL® Branding.



0 93351 01801 5

Lot No.:
Exp. date:
See back

Reseal Area

Drug Facts (continued)

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Inactive ingredients: FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, polybutene, propylene glycol, purified water, sorbitol special and white edible ink

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EXTRA STRENGTH PAIN RELIEF

acetaminophen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-182
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red (clear)	Score	no score
Shape	capsule (oblong)	Size	27mm
Flavor		Imprint Code	PC24
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-182-26	80 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/01/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-182) , analysis(51013-182)

Revised: 1/2020

PuraCap Pharmaceutical LLC