REGULAR 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.

Regular Strength Pain Relief

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 softgels (3,250 mg) in 24 hours for adults or 5 softgels (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if:

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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

Taking more than the recommended dose (overdose) may cause liver damage. 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	 take 2 softgels every 4 to 6 hours while symptoms last do not take more than 10 softgels in 24 hours do not use for more than 10 days unless directed by a doctor
children 6 years to under 12 years	 take 1 softgel every 4 to 6 hours while symptoms last do not take more than 5 softgels in 24 hours do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other information

• Store at 15°-30°C (59°-86°F) and avoid excessive heat.

Inactive ingredients

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

Questions or comments?

Call toll free: 1-855-215-8180

PRINCIPAL DISPLAY PANEL

Regular Strength Pain Relief

Acetaminophen 325mg 40 Liquid Gels

NDC 51013-402-25

*Compare to the active ingredient in TYLENOL® Regular Strength



DO NOT USE IF IMPRINTED SAFETY SEAL UNDEF CAP IS BROKEN

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Liver warming: This product contains acetaminophen. The maximum daily dose of this product is 10 softgels (3,250 mg) in 24 hours for children, 24 hours for adults or 5 softgels (1,625 mg) in 24 hours for children, Severe liver damage may occur

■adult takes more than 4,000 mg of acetaminophen in 24 hours ■child takes more than 5 doses in 24 hours, which is the maximum daily amount

taken with other drugs containing acetaminophen adult has 3 or more alcoholic drinks every day while using this product Symptoms may include: skin reddening blisters rash a skin reaction occurs, stop use and seek medical help right awa Allergy alert: acetaminophen may cause severe skin reactions.

If you are not sure whether a druc Do not use with any other drug containing acetaminopher contains acetaminophen, ask a doctor or pharmacist, prescription or nonprescription).

If you are allergic to acetaminophen or any of the inactive noredients in this product

Ask a doctor before use if the user has liver

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark TYLENOL® Regular Strength Orug Facts (continued under label)

DEMOULAS SUPERMARKETS INC. TEWKSBURY, MA 01876 Product Made in China

Lot No.:

Exp. Date:

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Store at 15°C-30°C (59°F-86°F) and avoid excessive heat. Other information

nactive ingredients FD&C red #40, FD&C yellow gelatin, glycerin, polyethylene glycol, povidone, propylene alycol, purified water, sorbitol sorbitan solution and white ink

Questions or comments? Call toll free: 1-855-215-8180

REGULAR STRENGTH PAIN RELIEF

acetaminophen capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51013-402

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D) **ACETAMINOPHEN** 325 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)	
PO VIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics			
Color	red (clear)	Score	no score
Shape	capsule (oblong)	Size	20 mm
Flavor		Imprint Code	PC17
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:51013-402-25	40 in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/14/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment			
Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-402), analysis(51013-402)

Revised: 1/2020 PuraCap Pharmaceutical LLC