

EXTRA STRENGTH PAIN RELIEVER- 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 Reliever

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 sorbitan solution and white edible ink

Questions or Comments?

Call : **1-888-309-9030**

PRINCIPAL DISPLAY PANEL - Bottle Label 20ct

DG Extra Strength Pain Reliever 20 Softgels

Acetaminophen 500mg

NDC 51013-172-15

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

NDC 51013-172-15

Compare to the active ingredient of TYLENOL® Extra Strength*

DG health

Extra Strength Pain Reliever
Acetaminophen 500 mg
Pain Reliever/
Fever Reducer

20 Softgels

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts
Active ingredient (in each softgel)
Acetaminophen 500 mg.....Pain reliever/fever reducer

Purpose
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

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

Drug Facts (continued under label)
 DISTRIBUTED BY
 DOLGENCORP, LLC (888) 309-9030
 100 MISSION RIDGE
 GOODLETTSVILLE, TN 37072
 MADE IN CHINA

100% SATISFACTION GUARANTEED!
 (888) 309-9030
 A0921

Lot No.: 3 51013 17215 5
Exp. Date:

PEEL HERE

Drug Facts (continued)
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	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?
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*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark TYLENOL® Extra Strength.

0606-00

PRINCIPAL DISPLAY PANEL - Bottle Label 40ct

DG Extra Strength Pain Reliever 40 Softgels

Acetaminophen 500mg

NDC 51013-172-25

* Compare to the active ingredient in TYLENOL® Extra Strength

NDC 51013-172-25

Compare to the active ingredient of TYLENOL® Extra Strength*

DG health

Extra Strength Pain Reliever
Acetaminophen 500 mg
Pain Reliever/
Fever Reducer

40 Softgels

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts
Active ingredient (in each softgel)
Acetaminophen 500 mg.....Pain reliever/fever reducer

Purpose
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

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.

Drug Facts (continued under label)
 DISTRIBUTED BY
 DOLGENCORP, LLC (888) 309-9030
 100 MISSION RIDGE
 GOODLETTSVILLE, TN 37072
 MADE IN CHINA

100% SATISFACTION GUARANTEED!
 (888) 309-9030
 A0922

Lot No.: 3 51013 17225 4
Exp. Date:

PEEL HERE

PRINCIPAL DISPLAY PANEL - Bottle Label 24ct

DG Extra Strength Pain Reliever 24 Softgels
 Acetaminophen 500mg
 NDC 51013-172-43

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

NDC 51013-172-43

DG health

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

BONUS!

Extra Strength

Pain Reliever

Acetaminophen 500 mg

Pain Reliever/
Fever Reducer

20 + 4 =

24 Softgels

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each softgel)
Acetaminophen 500 mg. _____ Pain reliever/fever reducer

Purpose

Temporarily relieves minor aches and pains due to:

- the common cold
- headache
- backache
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- 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 redness ■ hives ■ rash

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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

Drug Facts (continued under label)

DISTRIBUTED BY 100% SATISFACTION GUARANTEED!
 DOLGENCORP, LLC (888) 309-9030
 100 MISSION RIDGE
 GOODLETTSVILLE, TN 37072

MADE IN CHINA
 DG12-00

Lot No: 3 51013 17243 8
 Exp. Date:

Drug Facts (continued)

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	take 2 softgels every 6 hours while symptoms last
children under 12 years	do not take more than 6 softgels in 24 hours, unless directed by a doctor

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 sorbitan solution and white ink

Questions or comments?
 Call toll free: 1-888-309-9030

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McKel Consumer Healthcare Division, owner of the registered trademark **TYLENOL® Extra Strength**.

Drug Facts (continued)

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

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EXTRA STRENGTH PAIN RELIEVER

acetaminophen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-172
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)	
SORBITAN (UNII: 6O92ICV9RU)	

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:510 13-172-15	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2016	
2	NDC:510 13-172-25	40 in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2016	
3	NDC:510 13-172-43	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/08/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-172) , analysis(510 13-172)

Revised: 11/2019

PuraCap Pharmaceutical LLC