

**REGULAR 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.*

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**Regular Strength Pain Reliever**

**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
  - 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

**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 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**

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"> <li>• take 2 softgels every 4 to 6 hours while symptoms last</li> <li>• do not take more than 10 softgels in 24 hours</li> <li>• do not use for more than 10 days unless directed by a doctor</li> </ul>
children 6-11 years	<ul style="list-style-type: none"> <li>• take 1 softgel every 4 to 6 hours while symptoms last</li> <li>• do not take more than 5 softgels in 24 hours</li> <li>• do not use for more than 5 days unless directed by a doctor</li> </ul>
children under 6 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 Regular Strength Pain Reliever 20 Softgels

Acetaminophen 325mg

NDC 51013-173-15

\*Compare to the active ingredient in **TYLENOL®** Regular Strength

NDC 51013-173-15

**DC health**

Compare to the active ingredient of **TYLENOL®** Regular Strength\*

**Regular Strength Pain Reliever**  
Acetaminophen 325 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 325 mg...Pain reliever/fever reducer

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

**Uses**  
Temporarily relieves minor aches and pains due to:  
 ■ headache ■ 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

**Drug Facts (continued under label)**  
 100% SATISFACTION GUARANTEED!  
 DISTRIBUTED BY  
 DOLGENCORP, LLC  
 100 MISSION RIDGE  
 GOODLETTSVILLE, TN 37072  
 MADE IN CHINA  
 AO919

3 51013 17315 2

Lot No.:  
Exp. Date:

PEEL HERE

DG08-00

**Drug Facts (continued)**

- 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

**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 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.

**Drug Facts (continued)**

**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"> <li>■ take 2 softgels every 4 to 6 hours while symptoms last</li> <li>■ do not take more than 10 softgels in 24 hours</li> <li>■ do not use for more than 10 days unless directed by a doctor</li> </ul>
children 6-11 years	<ul style="list-style-type: none"> <li>■ take 1 softgel every 4 to 6 hours while symptoms last</li> <li>■ do not take more than 5 softgels in 24 hours</li> <li>■ do not use for more than 5 days unless directed by a doctor</li> </ul>
children under 6 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: 1-888-309-9030

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

**PRINCIPAL DISPLAY PANEL - Bottle Label 40ct**

DG Regular Strength Pain Reliever 40 Softgels

Acetaminophen 325mg

NDC 51013-173-25

\*Compare to the active ingredient in **TYLENOL®** Regular Strength

NDC 51013-173-25  
**Compare to the active ingredient in TYLENOL® Regular Strength\***

**Regular Strength Pain Reliever**  
 Acetaminophen 325 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 325 mg. *Pain reliever/fever reducer.*

**Purpose**  
 ■ temporarily relieves minor aches and pains due to:  
 ■ headache ■ 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 you take more than 10 softgels in 24 hours or more than 5 softgels in 24 hours for children, which is the maximum daily amount.  
 ■ take with other drugs containing acetaminophen  
 ■ add 3 or more alcoholic drinks every day while using this product  
 ■ Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin rash/itching ■ blisters ■ rash ■ 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  
 ■ if you are taking a blood thinner or aspirin

**Ask a doctor before use if the user has liver disease**  
 ■ if you are taking a blood thinner or aspirin  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist

**Drug Facts (continued under label)**  
 100% SATISFACTION GUARANTEED!  
 DISTRIBUTED BY  
 DOLGENCORP, LLC  
 100 MISSION RIDGE  
 GOODLETTSVILLE, TN 37072  
 MADE IN CHINA

Lot No.: 510131732511  
 Exp. Date:

**Drug Facts (continued)**

**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:** 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"> <li>take 2 softgels every 4 to 6 hours while symptoms last</li> <li>do not take more than 10 softgels in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
children 6-11 years	<ul style="list-style-type: none"> <li>take 1 softgel every 4 to 6 hours while symptoms last</li> <li>do not take more than 5 softgels in 24 hours</li> <li>do not use for more than 5 days unless directed by a doctor</li> </ul>
children under 6 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: 1-888-309-9030

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark TYLENOL® Regular Strength. D609-00

**PRINCIPAL DISPLAY PANEL - Bottle Label 24ct**  
 DG Regular Strength Pain Reliever 24 Softgels  
 Acetaminophen 325mg  
 NDC 51013-173-43  
 \*Compare to the active ingredient in TYLENOL® Regular Strength

NDC 51013-173-43  
**Compare to the active ingredient in TYLENOL® Regular Strength\***

**BONUS!**  
**Regular Strength Pain Reliever**  
 Acetaminophen 325 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 325 mg. *Pain reliever/fever reducer.*

**Purpose**  
 ■ temporarily relieves minor aches and pains due to:  
 ■ headache ■ 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 you take more than 10 softgels in 24 hours or more than 5 softgels in 24 hours for children, which is the maximum daily amount.  
 ■ take with other drugs containing acetaminophen  
 ■ add 3 or more alcoholic drinks every day while using this product  
 ■ Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin rash/itching ■ blisters ■ rash ■ 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  
 ■ if you are taking a blood thinner or aspirin

**Ask a doctor before use if the user has liver disease**  
 ■ if you are taking a blood thinner or aspirin  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist

**Drug Facts (continued under label)**  
 100% SATISFACTION GUARANTEED!  
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 100 MISSION RIDGE  
 GOODLETTSVILLE, TN 37072  
 MADE IN CHINA

Lot No.: 510131734315  
 Exp. Date:

**Drug Facts (continued)**

■ 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  
**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:  
 ■ skin reddening ■ blisters ■ rash  
 ■ 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  
 ■ if you are taking a blood thinner or aspirin

**Ask a doctor before use if the user has liver disease**  
 ■ if you are taking a blood thinner or aspirin  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist  
 ■ if you are taking a prescription or nonprescription drug containing acetaminophen, ask a doctor or pharmacist

**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.**

<b>Drug Facts (continued)</b>	
Keep out of reach of children. <b>Overdose warning:</b> 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.	
<b>Directions</b> ■ do not take more than directed (see Overdose warning)	
adults and children 12 years and over	<ul style="list-style-type: none"> <li>■ take 2 softgels every 4 to 6 hours while symptoms last</li> <li>■ do not take more than 10 softgels in 24 hours</li> <li>■ do not use for more than 10 days unless directed by a doctor</li> </ul>
children 6 years to under 12 years	<ul style="list-style-type: none"> <li>■ take 1 softgel every 4 to 6 hours while symptoms last</li> <li>■ do not take more than 5 softgels in 24 hours unless directed by a doctor</li> <li>■ do not use for more than 5 days unless directed by a doctor</li> </ul>
children under 6 years	ask a doctor
<b>Other information</b>	
■ Store at 15° C-30° C (59° F-86° F) and avoid excessive heat.	
<b>Inactive ingredients</b> FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink	
<b>Questions or comments?</b> Call toll free: 1-888-309-9039	

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

## REGULAR STRENGTH PAIN RELIEVER

acetaminophen capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:510 13-173
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	red (clear)	<b>Score</b>	no score
<b>Shape</b>	capsule (oblong)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	PC17
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:510 13-173-15	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2016	
2	NDC:510 13-173-25	40 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2016	
3	NDC:510 13-173-43	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	06/23/2016	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-173) , analysis(510 13-173)

Revised: 11/2019

PuraCap Pharmaceutical LLC