# EXTRA STRENGTH PAIN RELIEF- acetaminophen capsule, liquid filled Chain Drug Marketing Association Inc.

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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#### **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

#### 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 of age and over	<ul> <li>take 2 softgels every 6 hours while symptoms last</li> <li>do not take more than 6 softgels in 24 hours unless directed by a doctor</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years of age	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: 248-449-9300

#### PRINCIPAL DISPLAY PANEL - 40ct

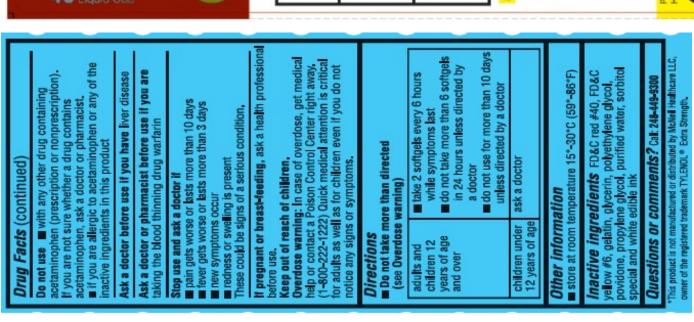
Extra Strength Pain Relief

Acetaminophen, 500mg 40 Liquid Gels

NDC 63868-863-40

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

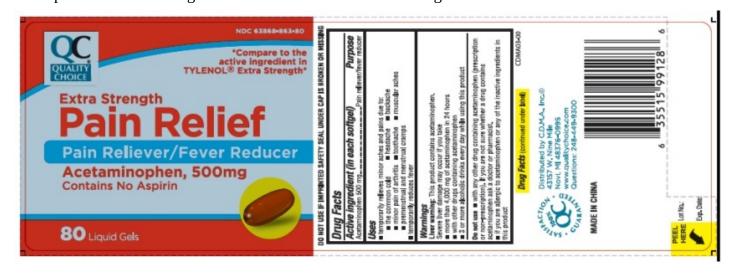




#### PRINCIPAL DISPLAY PANEL - 80ct

Extra Strength Pain Relief Acetaminophen, 500mg 80 Liquid Gels NDC 63868-863-80

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



Drug	Drug Facts (continued)	0)
Ask a Do	octor before use	Ask a Doctor before use if you have liver disease
thinning	thinning drug warfarin	
Stop use pain g fever g	Stop use and ask a doctor if pain gets worse or lasts m rever gets worse or lasts m	op 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 s ■ redne: These co	new symptoms occur redness or swelling is present lese could be signs of a seriou	<ul> <li>new symptoms occur</li> <li>redness or swelling is present</li> <li>These could be signs of a serious condition.</li> </ul>
Keep ou Overdos help or (1-800- for adult	if pregnant or breast-feeding, Keep out of reach of children Overdose Warning: In case of of help or contact a Poison Contro (1-800-222-1222) Quick medic for adults as well as for children notice any signs or symptoms.	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.
Direct do not	i take more than	Directions  do not take more than directed (see Overdose warning)
	adults and children 12 years of age and over	■ take 2 softgets every 6 hours while symptoms last on ord take more than 6 softgets in 24 hours unless directed by a doctor on use for more than 10 days unless directed by a doctor
	children under 12 years of age	ask a doctor
Other store	Other information store at room temperat	Other information store at room temperature 15°-30°C (59°-86°F)
Inactive ing FD&C red # 40, povidone, propy white edible ink	ve ingredient. d # 40, FD&C yel. e, propylene glyce ible ink	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
Questi	ons or comm	Questions or comments? at 248449300
his prod owner of	uct is not manufa the registered tra	This product is not manufactured or distributed by McNeil Healthcare LLC, owner of the registered trademark TYLENOL® Extra Strength.

### EXTRA STRENGTH PAIN RELIEF

acetaminophen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-863
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	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)			
PO VIDO NE (UNII: FZ989 GH94E)			
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

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>
ı	1 NDC:63868-863-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2016	
1	2 NDC:63868-863-80	80 in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2016	

Marketing Inform	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/22/2016	

## Labeler - Chain Drug Marketing Association Inc. (011920774)

Establishment			
Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(63868-863), analysis(63868-863)

Revised: 12/2019 Chain Drug Marketing Association Inc.