TYLENOL REGULAR STRENGTH- acetaminophen capsule, liquid filled
Johnson & Johnson Consumer 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.

Tylenol ®

Regular Strength

Drug Facts

Active ingredient (in each capsule)

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 capsules (3,250 mg) in 24 hours for adults or 5 capsules (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	▪ take 2 capsules every 4 to 6 hours while symptoms last ▪ do not take more than 10 capsules in 24 hours, unless directed by a doctor ▪ do not use for more than 10 days unless directed by a doctor
children 6 years to under 12	▪ take 1 capsule every 4 to 6 hours while symptoms last ▪ do not take more than 5 capsules in 24 hours

under 12 years	▪ do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other information

- each capsule contains: **potassium 25 mg**
- store between 20-25°C (68-77°F). Avoid high humidity.
- **do not use if carton is opened or if foil inner seal imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

ascorbyl palmitate, caprylic/capric triglycerides, dl-α-tocopherol, FD&C red no. 40, gelatin, glycerin, lecithin, medium chain triglycerides, mono-diglycerides, oleic acid, phosphatidylcholines (soya), polyethylene glycol, polyvinyl acetate phthalate, potassium acetate, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-487-20

TYLENOL®

Actual Size

Acetaminophen

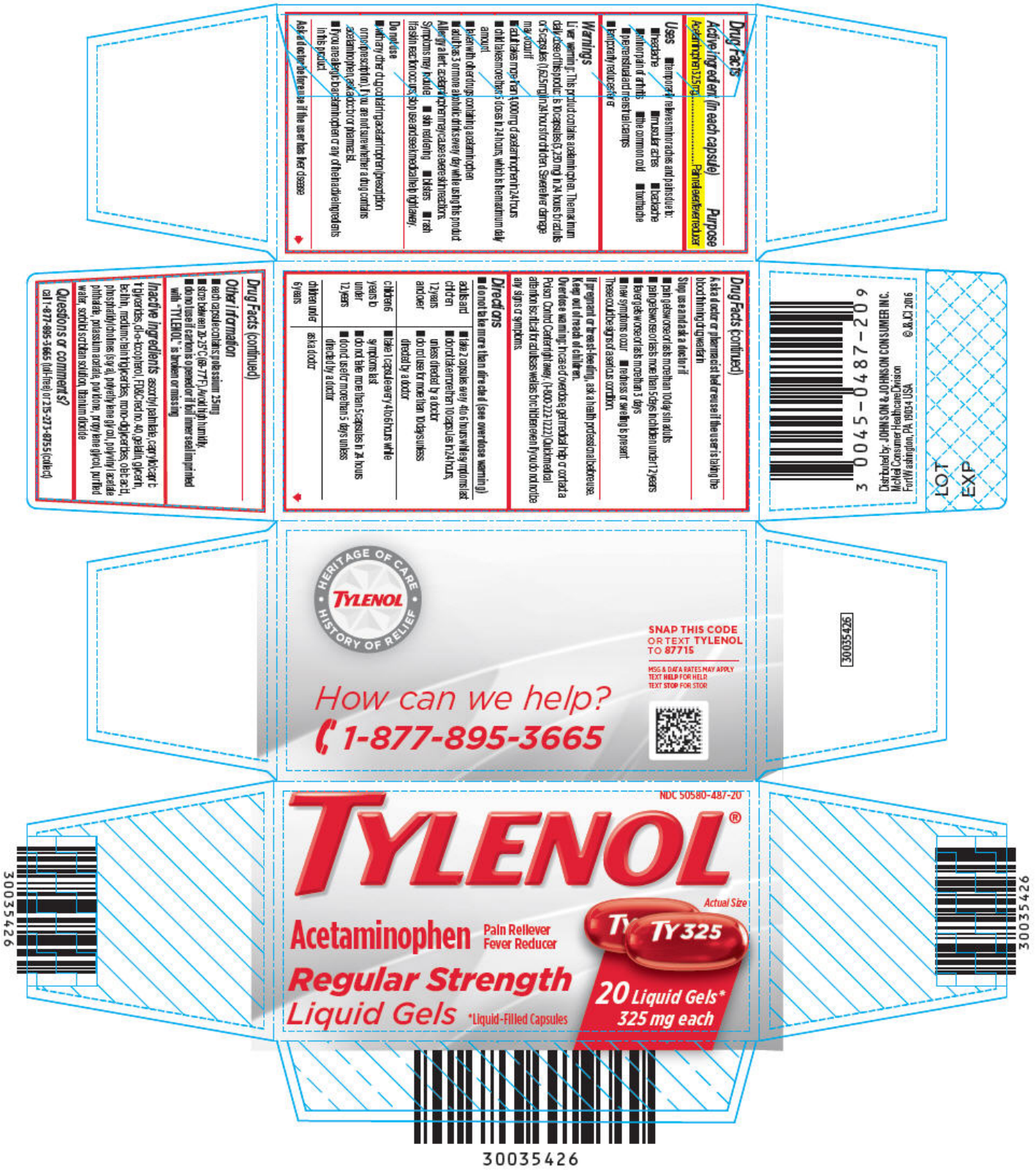
Pain Reliever
Fever Reducer

Regular Strength

Liquid Gels

*Liquid-Filled Capsules

20 Liquid Gels*
325 mg each



TYLENOL REGULAR STRENGTH

acetaminophen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-487
Route of Administration	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
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLEIC ACID (UNII: 2UMI9U37CP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POTASSIUM ACETATE (UNII: M911911U02)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	TY;325
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-487-20	1 in 1 CARTON	01/05/2016	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-487-90	1 in 1 CARTON	01/05/2016	
2		90 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/05/2016	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023 Johnson & Johnson Consumer Inc.