

**TYLENOL REGULAR STRENGTH- acetaminophen tablet**  
**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.*

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**TYLENOL**

**Regular Strength**

**Drug Facts**

**Active ingredient (in each tablet)**

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 tablets (3,250 mg) in 24 hours for adults or 5 tablets (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 tablets every 4 to 6 hours while symptoms last</li> <li>▪ do not take more than 10 tablets 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>
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children 6 years to under 12 years	<ul style="list-style-type: none"> <li>▪ take 1 tablet every 4 to 6 hours while symptoms last</li> <li>▪ do not take more than 5 tablets 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 between 20-25°C (68-77°F)
- **do not use if carton is opened. Do not use if foil inner seal imprinted with "TYLENOL" is broken or missing**

**Inactive ingredients**

magnesium stearate, modified starch, powdered cellulose, pregelatinized starch, sodium starch glycolate

**Questions or comments?**

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

**PRINCIPAL DISPLAY PANEL**

NDC 50580-495-01

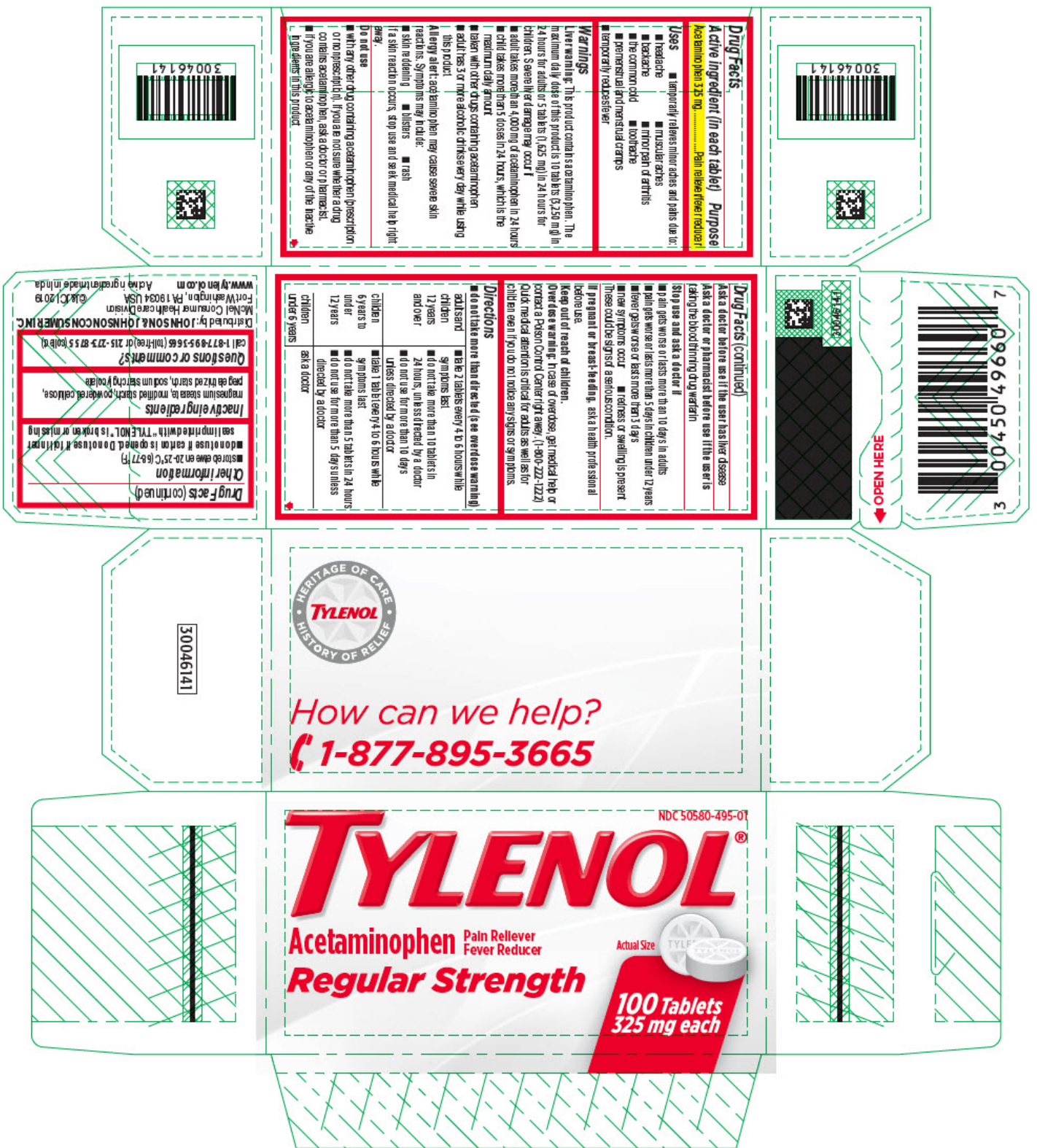
TYLENOL®

Acetaminophen  
Pain Reliever  
Fever Reducer

Regular Strength

Actual Size

100 Tablets  
325 mg each



## TYLENOL REGULAR STRENGTH

acetaminophen tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-495
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

**Product Characteristics**

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	325;TYLENOL
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-495-01	1 in 1 CARTON	12/01/2019	
1		100 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	12/01/2019	

**Labeler** - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023

Johnson &amp; Johnson Consumer Inc.