

TYLENOL REGULAR STRENGTH- acetaminophen tablet, film coated
Kenvue Brands LLC

TYLENOL Regular Strength

Drug Facts

Active ingredient (in each caplet)

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 caplets (3,250 mg) in 24 hours for adults or 5 caplets (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
- is a child with pain of arthritis

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">▪ take 2 caplets every 4 to 6 hours while symptoms last▪ do not take more than 10 caplets 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 years | <ul style="list-style-type: none">▪ take 1 caplet every 4 to 6 hours while symptoms last▪ do not take more than 5 caplets in 24 hours▪ do not use for more than 5 days unless directed by a doctor |

children
under 6
years

ask a doctor

Other information

- store between 20-25°C (68-77°F)
- do not use if blister unit is torn or broken

Inactive ingredients

carnauba wax, corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

325mg

NDC 50580-458-11

To re-order reference the NDC Code

TYLENOL[®]

Acetaminophen Pain Reliever - Fever Reducer

Regular Strength

100 Caplets

325 mg each

10 Blister Cards

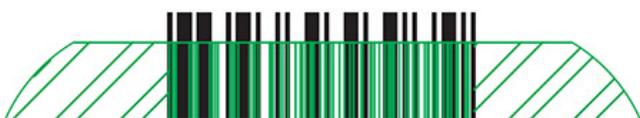
with

10 Individual Blisters

SMART PACKAGING
DESIGNED FOR HEALTH
CARE PROFESSIONALS

FOR HOSPITAL USE ONLY. NOT FOR HOUSEHOLD USE.

PACKAGE IS NOT CHILD-RESISTANT.



Regular Strength

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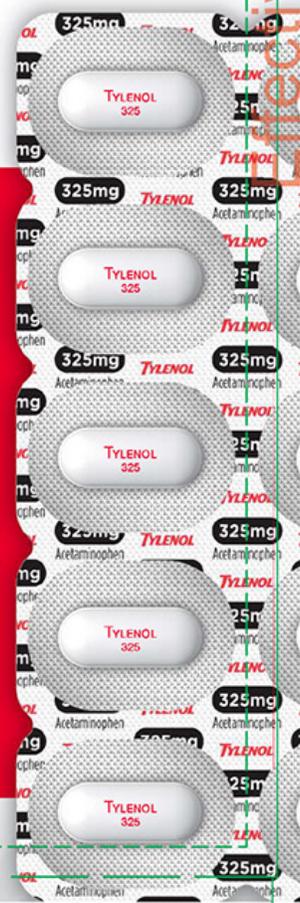
Blister pack
configuration for
ease of inventory

Clear dosing
information for
ease of identification

Perforation and
rounded corners for
easy dispensing

Scannable LOT/EXP
information on
bottom of carton

Window



325mg

TYLENOL®

Acetaminophen Pain Reliever - Fever Reducer

Regular Strength

Important: Read all product information before using.
Keep this box for important information.

Drug Facts

| Active ingredient (in each caplet) | Purpose |
|------------------------------------|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |

Uses

- temporarily relieves minor aches and pains due to:
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Ask a doctor before use if the user

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Drug Facts (continued)

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| children under 6 years | ask a doctor |

Other information

- store between 20-25°C (68-77°F)
- do not use if blister unit is torn or broken

Inactive ingredients: carnauba wax, corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

Questions or comments? Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Active ingredient made in India

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA

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Visit us at www.tylenol.com or call toll-free 1-877-TYLENOL (1-877-895-3665)

TYLENOL REGULAR STRENGTH

acetaminophen tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50580-458 |
| 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 |
|---|----------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POWDERED CELLULOSE (UNII: SMD1X3XO9M) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SHELLAC (UNII: 46N107B71O) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D) | |

Product Characteristics

| | | | |
|-----------------|------------------------------|---------------------|-------------|
| Color | white (White with red print) | Score | no score |
| Shape | OVAL | Size | 16mm |
| Flavor | | Imprint Code | Tylenol;325 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:50580-458-11 | 10 in 1 CARTON | 07/17/2020 | |
| 1 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:50580-458-50 | 1 in 1 CARTON | 07/17/2020 | |
| 2 | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

| | | | | |
|------------------------------|---------------------------|--|-----------------------------|---------------------------|
| 3 | NDC:50580-458-10 | 1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/17/2020 | 07/31/2025 |
| Marketing Information | | | | |
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| | OTC Monograph Drug | M013 | 07/17/2020 | |

Labeler - Kenvue Brands LLC (118772437)

Revised: 1/2026

Kenvue Brands LLC