

TYLENOL 8HR- acetaminophen tablet, film coated, extended release
Kenvue Brands LLC

Tylenol® 8HR

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 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 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 and over	<ul style="list-style-type: none">▪ take 2 caplets every 8 hours with water▪ swallow whole; do not crush, chew, split or dissolve▪ do not take more than 6 caplets in 24 hours▪ do not use for more than 10 days unless directed by a doctor
children under 12 years	<ul style="list-style-type: none">▪ do not use

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

carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, modified starch, povidone, powdered cellulose, pregelatinized

starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-309-02

TYLENOL[®] 8HR
MUSCLE ACHES & PAIN

Acetaminophen
Extended-release tablets

Pain Reliever / Fever Reducer

For Up to 8 Hours Relief of Minor Muscle Aches & Pain

*Capsule-Shaped Bi-Layer Tablets

Actual Size

100 Caplets*
650 mg each

Drug Facts

Active ingredient (in each caplet)

Purpose

Acetaminophen 650 mg..... Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - muscle aches
 - backache
 - minor pain of arthritis
 - toothache
- premenstrual and menstrual cramps
- headache
- the common cold
- temporarily reduces fever

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- hives
- 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 you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Drug Facts (continued)

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 breastfeeding, 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 8 hours with waterswallow whole; do not crush, chew, split or dissolvedo not take more than 6 caplets in 24 hoursdo not use for more than 10 days unless directed by a doctor
children under 12 years	<ul style="list-style-type: none">do not use

Other information

- store between 20-25°C (68-77°F)
- do not use if caplet is opened. Do not use if foil inner seal imprinted with "TYLENOL" is broken or missing

Inactive ingredients camellia wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, modified starch, polydextrose, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?

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



How can we help?
1-877-895-3665

NDC 50580-309-02

TYLENOL[®] 8HR

MUSCLE ACHES & PAIN

Acetaminophen
Extended-release tablets

Pain Reliever / Fever Reducer

For Up to 8 Hours Relief of Minor Muscle Aches & Pain

*Capsule-Straped BI-Layer Tablets

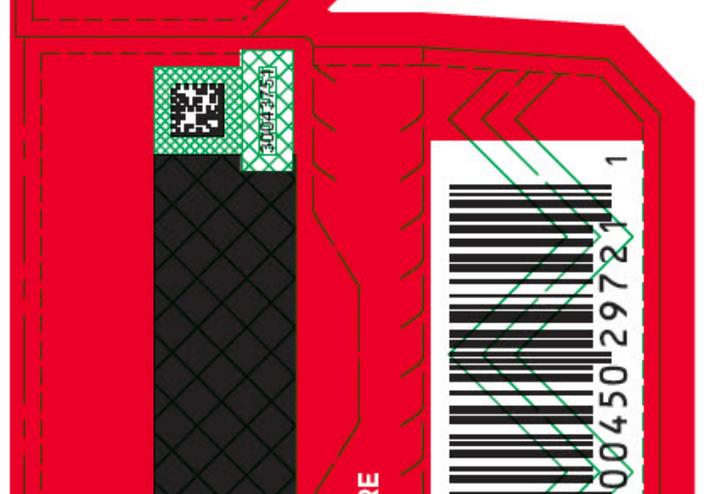


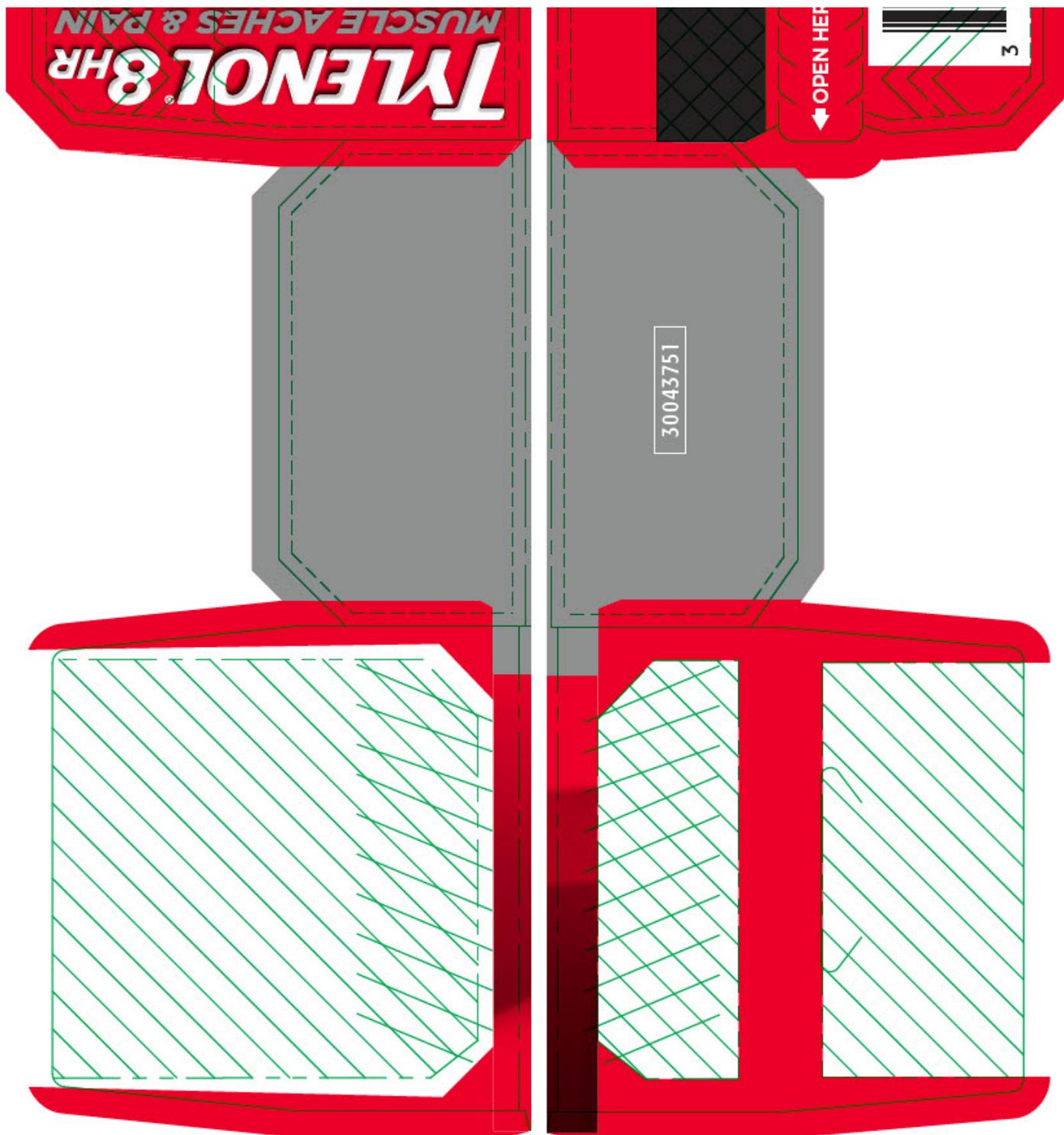
Actual Size

100 Caplets*
650 mg each



Acetaminophen
Extended-release tablets
Pain Reliever / Fever Reducer
For Up to 8 Hours Relief of Minor Muscle Aches & Pain
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
©J&JCI 2019
Contains No Aspirin





TYLENOL 8HR

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-309
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	TYLENOL;ER
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-309-01	1 in 1 CARTON	01/18/2016	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-309-02	1 in 1 CARTON	01/18/2016	
2		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
NDA	NDA019872	01/18/2016	

Labeler - Kenvue Brands LLC (118772437)