TYLENOL 8HR- acetaminophen tablet, film coated, extended release
Johnson & Johnson Consumer Inc.

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	▪ 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	▪ 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

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Drug Facts (continued)

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HERITAGE OF CARE • TYLENOL • HERITAGE OF CARE

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

NDC 50580-309-02

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Acetaminophen
Extended-release tablets

Pain Reliever / Fever Reducer

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

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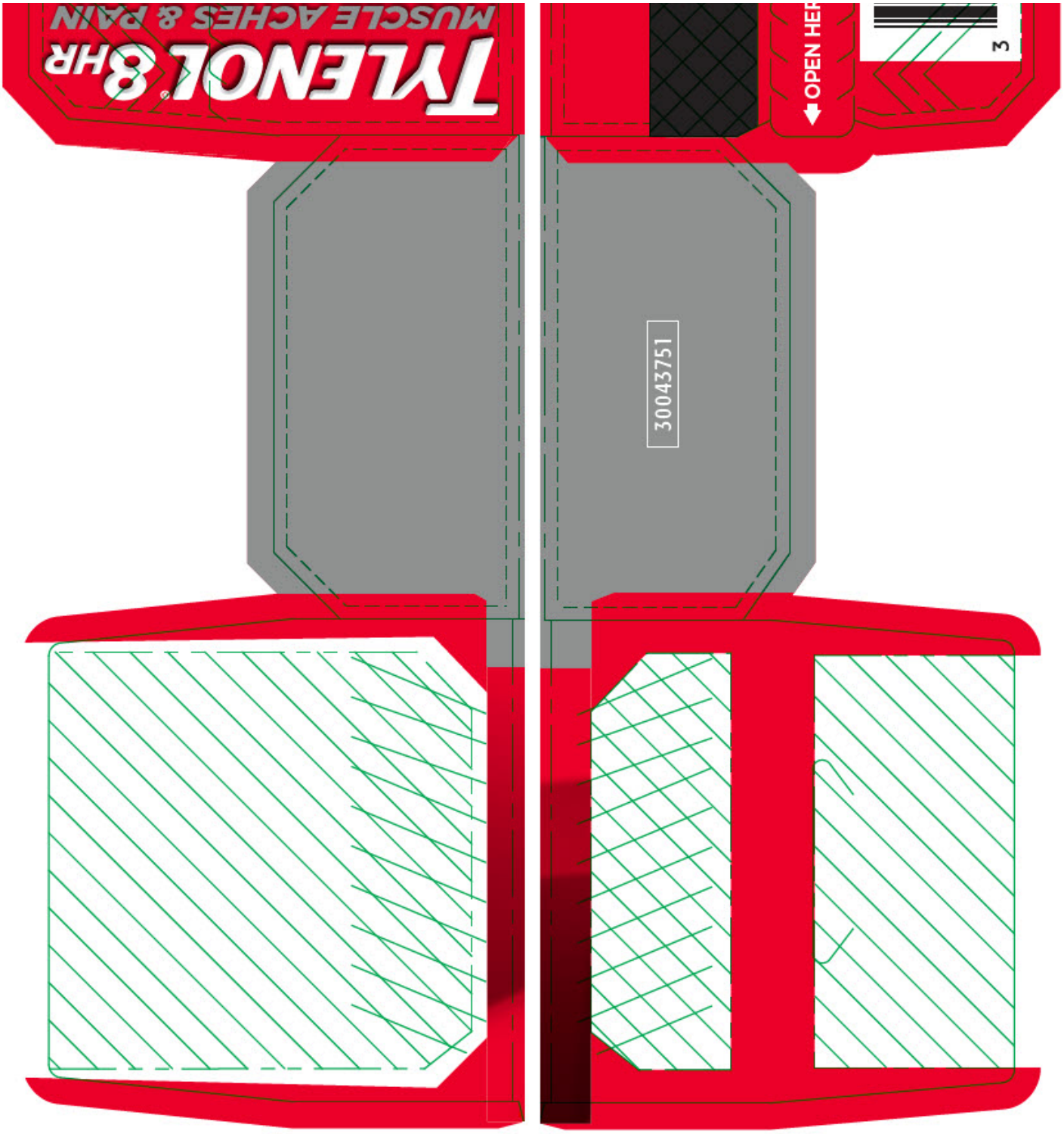
Extended-release tablets
Pain Reliever / Fever Reducer
For Up to 8 Hours Relief of Minor Muscle Aches & Pain

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA

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 - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023 Johnson & Johnson Consumer Inc.