

**TYLENOL 8 HR MUSCLE ACHES AND PAIN- acetaminophen tablet, film coated, extended release**

**Johnson & Johnson Consumer Inc.**

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**Tylenol® 8HR Muscle Aches & Pain**

***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)

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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	■ ask a doctor

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**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**

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

**Questions or comments?**

call **1-800-458-2014** (toll-free) or **215-273-8755** (collect)

**PRINCIPAL DISPLAY PANEL**

NDC 50580-576-02

**TYLENOL<sup>®</sup> 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)**  
Acetaminophen 650 mg. **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 the maximum daily amount.

- do not take more than 12 tablets in 24 hours, which is the maximum daily amount
- do not take 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 redness
- skin itching
- hives
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- if you are taking or have taken 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 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 and over
- do not take for more than 10 days unless directed by a doctor

children under 12 years

- ask a doctor

**Other information**

Store between 20°-25° (68°-77°). Do not use if full inner seal is broken. Do not use if the caplet is broken or missing. Imprinted with "TYLENOL" is broken or missing.

**Inactive ingredients**

hydroxyethylcellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, pregelatinized starch, sodium starch glycolate, stearic acid

**Questions or comments?**

call 1-800-458-2014 (for help) or 215-273-8755 (toll-free)



Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division Fort Washington, PA 19094  
USA. Made in India. Pat. www.jjcpatents.com

**Contains No Aspirin**

**TYLENOL 8HR**  
**MUSCLE ACHES & PAIN**  
Acetaminophen  
Extended-release tablets  
Pain Reliever / Fever Reducer  
For Up To 8 Hours Relief of Minor Muscle Aches & Pain

OPEN HERE



How can we help?  
**1-800-458-2014**

NDC 50580-576-02

**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**

**TYLENOL 8 HR MUSCLE ACHES AND PAIN**

acetaminophen tablet, film coated, extended release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-576
<b>Route of Administration</b>	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
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
MAGNESIUM STEARATE (UNII: 70097M6130)	

**Product Characteristics**

Color	white	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	TYLENOL;ER
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-576-01	1 in 1 CARTON	01/30/2024	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-576-02	1 in 1 CARTON	01/30/2024	
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
ANDA	ANDA211544	01/30/2024	

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

Revised: 1/2024

Johnson &amp; Johnson Consumer Inc.