



150% ACTUAL SIZE - FOR REVIEW ONLY



ACTUAL SIZE



See New Warning NDC 50580-785-10

# TYLENOL<sup>®</sup> 8HR

## ARTHRITIS PAIN

Acetaminophen extended-release tablets Pain Reliever/Fever Reducer  
For The Temporary Relief Of Minor Arthritis Pain

Distributed by:  
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Division of McNE L-PPC, Inc.  
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Caplets<sup>\*</sup>  
*\*Capsule-Shaped, Bi-Layer Tablets*

100 CAPLETS 650 mg each

Contains No Aspirin

OPEN TO READ DIRECTIONS AND ADDITIONAL DRUG FACTS INFORMATION  
Do not use if neck wrap or foil inner seal imprinted with "SAFETY SEAL<sup>®</sup>" is broken.

3 0045-0838-216

| Active ingredient (in each caplet) | Purpose                     |
|------------------------------------|-----------------------------|
| Acetaminophen 650 mg               | Pain reliever/fever reducer |

**Uses**

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

COVER, PAGE 1

|   |   |
|---|---|
| <p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>more than 6 caplets in 24 hours, which is the maximum daily amount</li> <li>with other drugs containing acetaminophen</li> <li>3 or more alcoholic drinks every day while using this product</li> </ul> <p><b>Allergy alert:</b> acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>skin reddening</li> <li>blisters</li> <li>rash</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if you are allergic to acetaminophen or any of the inactive ingredients in this product</li> </ul> | <p><b>Drug Facts (continued)</b></p> <p><b>Ask a doctor before use if you have liver disease</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>pain gets worse or lasts more than 10 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>new symptoms occur</li> <li>redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> 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.</p> |
|---|---|

BACK OF COVER, PAGE 2

|  |   |
|--|---|
| <p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <p><b>do not take more than directed (see overdose warning)</b></p> <p>adults</p> <ul style="list-style-type: none"> <li>take 2 caplets every 8 hours with water</li> <li>swallow whole; do not crush, chew, split or dissolve</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul> <p>under 18 years of age</p> <ul style="list-style-type: none"> <li>ask a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F).</li> <li>do not use if neck wrap or foil inner seal imprinted with "SAFETY SEAL<sup>®</sup>" is broken</li> </ul> | <p><b>Drug Facts (continued)</b></p> <p><b>Inactive ingredients</b> carnauba wax, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p><b>Questions or comments?</b><br/>call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)</p> <p>Distributed by:<br/>McNeil Consumer Healthcare<br/>Division of McNE L-PPC, Inc.<br/>Fort Washington, PA 19034 USA<br/>©McNE L-PPC, INC. 2013 Visit us at <a href="http://www.tylenol.com">www.tylenol.com</a></p> <p><b>TYLENOL<sup>®</sup> 8 HR ARTHRITIS PAIN</b><br/>Acetaminophen extended-release tablets<br/>100 caplets - 650 mg each</p> |
|--|---|

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LOT:

EXP:

PEEL

BASE LABEL, PAGE 3





150% ACTUAL SIZE FOR REVIEW ONLY



ACTUAL SIZE

00000000

See New Warning

NDC 50580-783-25

Push & Turn Cap

# TYLENOL<sup>®</sup> 8HR

## ARTHRITIS PAIN

Acetaminophen extended-release tablets Pain Reliever/Fever Reducer  
For The Temporary Relief Of Minor Arthritis Pain

225 CAPLETS 650 mg each

Caplets<sup>\*</sup>  
\*Capsule-Shaped Bi-Layer Tablets



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### Drug Facts

**Active ingredient (in each caplet)** Purpose  
Acetaminophen 650 mg..... Pain reliever/fever reducer

### Uses

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

### 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

Contains No Aspirin

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EMC/EL-PPC, INC., 2013  
Visit us at [www.tylenol.com](http://www.tylenol.com) or call toll-free 1-877-TYLENOL (1-877-895-5665)

Push & Turn Cap

225 CAPLETS 650 mg each

Capsule-Shaped Bi-Layer Tablets

Acetaminophen extended-release tablets Pain Reliever/Fever Reducer

ARTHRITIS PAIN

# TYLENOL<sup>®</sup> 8HR

### Drug Facts (continued)

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
- take 2 caplets every 8 hours with water
  - swallow whole; do not crush, chew, spit 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
  - ask a doctor
- under 18 years of age
- ask a doctor

### Other information

- store at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F).
- do not use if carton is opened or neck wrap or foil inner seal imprinted with "SAFETY SEAL" is broken

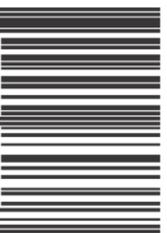
### Inactive ingredients

canthaxanthin, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

### Questions or comments?

call 1-877-895-5665 (toll-free) or 215-273-8755 (collect)

3 0045-0838-377



EXP:

LOT:

NDC 50580-783-25

See New Warning

Push & Turn Cap

# TYLENOL<sup>®</sup> 8HR

Acetaminophen extended-release tablets  
Pain Reliever/Fever Reducer  
For The Temporary Relief Of Minor Arthritis Pain

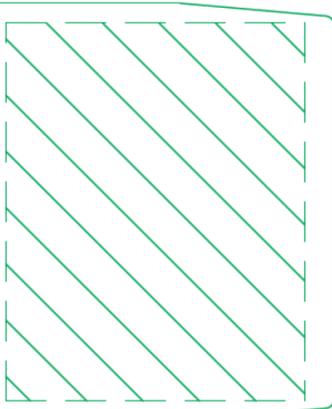
225 CAPLETS 650 mg each

Capsule-Shaped Bi-Layer Tablets



|   |   |  |                              |  |
|---|---|--|------------------------------|--|
| <p>00000000</p>  <p>00000000</p> | <p><b>Active ingredient (in each caplet)</b></p> <p>Acetaminophen 650 mg.....Pain reliever/fever reducer</p>  | <p><b>Purpose</b></p> <p>Pain reliever/fever reducer</p>   | <p><b>READ THE LABEL</b></p> | <p>professional be ore use.</p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> In case of ove dose, get medica 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.</p> <p><b>Directions</b></p> <p>do not take more than directed (see overdose warning)</p> <p><b>Adults:</b></p> <ul style="list-style-type: none"> <li>take 2 caplets every 8 hours with water</li> <li>swallow whole; do not crush, chew, split or dissolve</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul> <p><b>Under 18 years of age:</b> ask a doctor</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F).</li> <li>do not use if neck wrap or foil inner seal imprinted with "SAFETY SEAL®" is broken</li> </ul> <p><b>Inactive ingredients</b> ca naubawax, co n starch, hyd oxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p><b>Questions or comments?</b></p> <p>call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)</p> <p>Distributed by: McNeil Consumer Hea thcare Division of McNEIL-PPC, Inc. Fort Washington, PA 19034 USA</p> <p>©McNEIL-PPC, INC. 2013</p> <p>Visit us at <a href="http://www.tylenol.com">www.tylenol.com</a></p> |
|   | <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>temporarily relieves minor aches and pains due to:             <ul style="list-style-type: none"> <li>minor pain of arthritis</li> <li>muscular aches</li> <li>backache</li> <li>premenstrual and menstrual cramps</li> <li>the common cold</li> <li>headache</li> <li>toothache</li> </ul> </li> <li>temporarily reduces fever</li> </ul> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This p oduct 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. <b>Allergy alert:</b> 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. <b>Do not use</b> with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pha macist. if you are allergic to acetaminophen or any of the inactive ingredients in this p oduct. <b>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 warfa in. Stop use and ask a doctor if</b> 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. <b>If pregnant or breast-feeding,</b> ask a hea th</p> | <p><b>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</b></p> <p>NDC 50580-783-25</p> <p><b>TYLENOL® 8HR</b></p> <p><b>ARTHRITIS PAIN</b></p> <p>Acetaminophen extended-release tablets</p> <p>Pain Reliever/Fever Reducer</p> <p>For The Temporary Relief Of Minor Arthritis Pain</p> <p>225 CAPLETS<br/>650 mg each</p> <p><b>Caplets*</b></p> <p>Capsule-Shaped Bi-Layer Tablets</p>  |                              |  |

(b) (4)



**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

- 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

under 18 years of age

■ ask a doctor

**Other information**

- store at 20-25°C (68-77°F). Avoid excessive heat, 40°C (104°F).
- do not use if carton is opened or neck wrap or foil inner seal imprinted with "SAFETY SEAL" is broken

**Inactive ingredients**

canthaxanthin, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polydioxane, 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)

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NDC 50580-783-29

**See New Warning**

**TYLENOL 8HR**

**Push & Turn Cap**

*Acetaminophen extended-release tablets*  
*Pain Reliever/Fever Reducer*  
*For The Temporary Relief Of Minor Arthritis Pain*

**Caplets\***  
*\*Capsule-Shaped Bi-Layer Tablets*

**290 CAPLETS 650 mg each**



**TYLENOL 8HR**

**ARTHRITIS PAIN**

*Acetaminophen extended-release tablets Pain Reliever/Fever Reducer*  
*For The Temporary Relief Of Minor Arthritis Pain*

**290 CAPLETS 650 mg each**

**Caplets\***  
*\*Capsule-Shaped Bi-Layer Tablets*

**Push & Turn Cap**

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**Contains No Aspirin**

NDC 50580-783-29

**See New Warning**

**TYLENOL 8HR**

**ARTHRITIS PAIN**

*Acetaminophen extended-release tablets Pain Reliever/Fever Reducer*  
*For The Temporary Relief Of Minor Arthritis Pain*

**290 CAPLETS 650 mg each**

**Caplets\***  
*\*Capsule-Shaped Bi-Layer Tablets*



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**Drug Facts**

**Active ingredient (in each caplet)** Purpose  
Acetaminophen 650 mg... Pain reliever/fever reducer

**Uses**

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

EXP  
LOT

3 0045-0838-29 2

**Active ingredient (in each caplet) Purpose**  
**Acetaminophen 650 mg.....Pain reliever/fever reducer**

**Uses**

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

◀ **READ THE LABEL** ▶

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

NDC 50580-783-29

**TYLENOL® 8HR**

**ARTHRITIS PAIN**

*Acetaminophen extended-release tablets*  
*Pain Reliever/Fever Reducer*

*For The Temporary Relief Of Minor Arthritis Pain*

290 CAPLETS  
650 mg each

**Caplets\*** 

\*Capsule-Shaped Bi-Layer Tablets

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:**

- 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

**Under 18 years of age:**

- ask a doctor

**Other information**

- store at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F).
- do not use if neck wrap or foil inner seal imprinted with "SAFETY SEAL®" is broken

**Inactive ingredients**

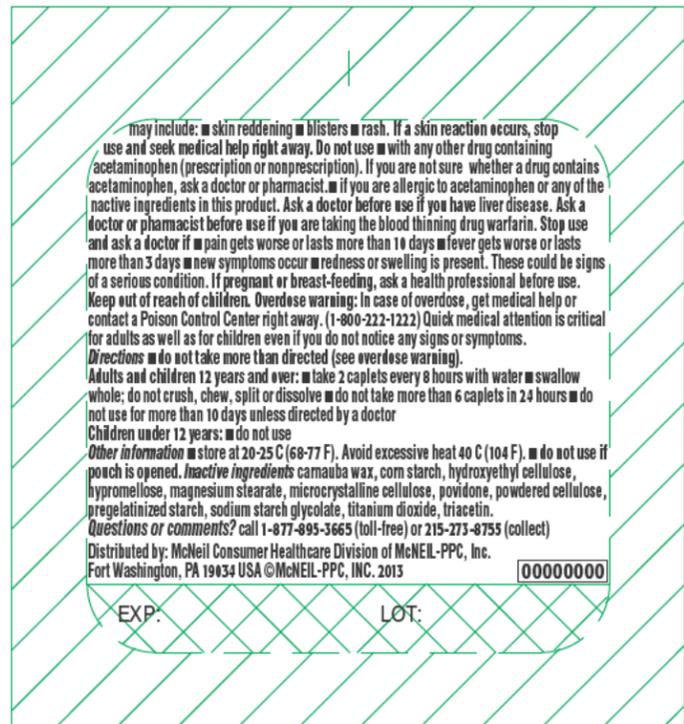
carnauba wax, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

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

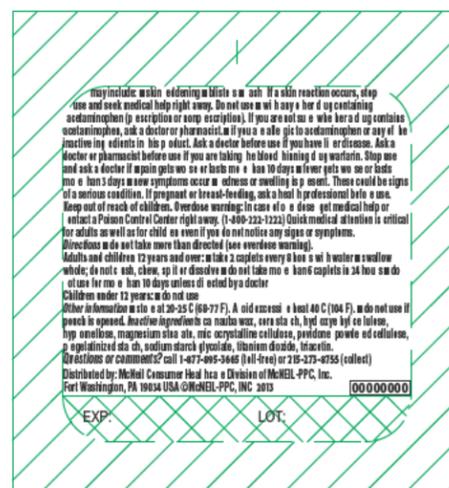
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150% ACTUAL SIZE - FOR REVIEW ONLY



ACTUAL SIZE



NDC 50580-309-02 See New Warning

# TYLENOL® 8HR\*

Acetaminophen extended-release tablets Pain Reliever / Fever Reducer

\*FOR UP TO 8 HOUR RELIEF OF MINOR MUSCLE ACHES & PAIN  
HEADACHE | BACKACHE | MINOR PAIN OF ARTHRITIS

100 CAPLETS 650 MG EACH  CAPLETS\*  
\*Capsule-Shaped Bi-Layer Tablets

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OPEN TO READ DIRECTIONS AND ADDITIONAL DRUG FACTS INFORMATION  
Do not use if neck wrap or foil inner seal imprinted with "SAFETY SEAL®" is broken.

**Drug Facts**

| Active ingredient (in each caplet) | Purpose                     |
|------------------------------------|-----------------------------|
| Acetaminophen 650 mg               | Pain reliever/fever reducer |

**Uses**

- temporarily relieves minor aches and pains due to:
  - muscular aches
  - headache
- backache
- minor pain of arthritis
- temporarily reduces fever

COVER, PAGE 1

**Drug Facts (continued)**

**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
- w th 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**

- w th any other drug containing acetaminophen (prescription o 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

**Drug Facts (continued)**

**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.

BACK OF COVER, PAGE 2

**Drug Facts (continued)**

**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 caplets every 8 hours w th water</li> <li>■ swallow whole; do not crush, chew, split or dissolve</li> <li>■ do not take more than 6 caplets in 24 hours</li> <li>■ do not use for more than 10 days unless directed by a doctor</li> </ul> |
| children under 12 years               | <ul style="list-style-type: none"> <li>■ do not use</li> </ul>   |

**Other information**

- store at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F).
- do not use if neck wrap or foil inner seal imprinted with "SAFETY SEAL®" is broken

**Drug Facts (continued)**

**Inactive ingredients** ca nauba wax, co n starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, 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)

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**TYLENOL® 8 HR**  
Acetaminophen extended-release tablets  
100 caplets - 650 mg each



BASE LABEL, PAGE 3





150% ACTUAL SIZE FOR REVIEW ONLY



ACTUAL SIZE



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**Questions or comments?**  
call 1-877-895-5665 (toll-free) or 215-273-8755 (collect)

**Inactive ingredients** carmalum wax, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, titanium

**Other information**  
■ store at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F).  
■ do not use if carton is opened or neck wrap or toll breaker seal imprinted with "SAFETY SEALER" is broken

**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

**Drug Facts (continued)**  
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.

NDC 50580-309-03

See New Warning

# TYLENOL<sup>®</sup> 8HR<sup>\*</sup>

Acetaminophen extended-release tablets Pain Reliever / Fever Reducer

\*FOR UP TO 8 HOUR RELIEF OF MINOR  
**MUSCLE ACHES & PAIN**  
HEADACHE | BACKACHE | MINOR PAIN OF ARTHRITIS

225 CAPLETS  
650 MG EACH



CAPLETS<sup>\*</sup>

\*Capsule - Shaped Bi-Layer Tablets

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NDC 50580-309-03

See New Warning

# TYLENOL<sup>®</sup> 8HR<sup>\*</sup>

Acetaminophen extended-release tablets Pain Reliever / Fever Reducer

\*FOR UP TO 8 HOUR RELIEF OF MINOR  
**MUSCLE ACHES & PAIN**  
HEADACHE | BACKACHE | MINOR PAIN OF ARTHRITIS

225 CAPLETS  
650 MG EACH



CAPLETS<sup>\*</sup>

\*Capsule - Shaped Bi-Layer Tablets

# TYLENOL<sup>®</sup> 8HR<sup>\*</sup>

Acetaminophen extended-release tablets  
Pain Reliever / Fever Reducer

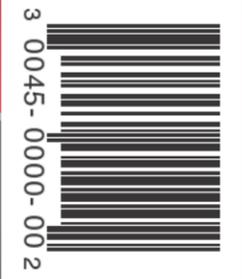
225 CAPLETS  
650 MG EACH



CAPLETS<sup>\*</sup>

\*Capsule - Shaped Bi-Layer Tablets

**Contains No Aspirin**



3 0045-0000-002

EXP. LOT

## Drug Facts

**Active ingredient (in each caplet) Purpose**  
Acetaminophen 650 mg.....Pain reliever/fever reducer

## Uses

- Temporarily relieves minor aches and pains due to:
  - muscular aches
  - backache
  - headache
  - minor pain of arthritis
- 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
- Aller gy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:
  - skin redness
  - 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

## 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.



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| Active ingredient (in each caplet) | Purpose                     |
|------------------------------------|-----------------------------|
| Acetaminophen 650 mg               | Pain reliever/fever reducer |

**Uses**

- temporarily relieves minor aches and pains due to:
  - muscular aches
  - backache
  - headache
  - minor pain of arthritis
- 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.**

**READ THE LABEL**

NDC 50580-309-03

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

**TYLENOL® 8HR\***  
Acetaminophen extended-release tablets  
Pain Reliever / Fever Reducer

\*FOR UP TO 8 HOUR RELIEF OF MINOR MUSCLE ACHES & PAIN  
HEADACHE | BACKACHE | MINOR PAIN OF ARTHRITIS

225 CAPLETS  
650 MG EACH



CAPLETS\*  
\*Capsule-Shaped Bi-Layer Tablets

**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 at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F).
- do not use if neck wrap or foil inner seal imprinted with "SAFETY SEAL®" is broken

**Inactive ingredients**

carnaubawax, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, 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)

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