Tylenol® 8 HR Arthritis 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:
  - 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

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 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 50580-783-32

TYLENOL® 8HR

ARTHHRITIS PAIN
Acetaminophen
Extended-release tablets
Pain Reliever / Fever Reducer
For The Temporary Relief
Of Minor Arthritis Pain
*Capsule-Shaped
Bi-Layer Tablets
Actual Size
100 Caplets*
650 mg each
**Drug Facts**

*Active ingredient (in each caplet)*

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 650 mg</td>
<td>Pain reliever/fever reducer</td>
</tr>
</tbody>
</table>

**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
- 5 or more alcoholic drinks every day while using this product

*Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:*
- skin redness
- blisters
- rash

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

**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)**

<table>
<thead>
<tr>
<th>Adults</th>
<th>Under 10 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 caplets every 8 hours with water</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>swallow whole; do not crush, chew, split or dissolve</td>
<td></td>
</tr>
<tr>
<td>do not take more than 6 caplets in 24 hours</td>
<td></td>
</tr>
<tr>
<td>do not use for more than 10 days unless directed by a doctor</td>
<td></td>
</tr>
</tbody>
</table>

**Other Information**

- store between 20-25°C (68-77°F)
- do not use if bottle is opened. Replace if seal is broken
TYLENOL 8 HR ARTHRITIS PAIN
acetaminophen tablet, extended release

<table>
<thead>
<tr>
<th>Product Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type</td>
</tr>
<tr>
<td>Route of Administration</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Active Ingredient/Active Moiety</th>
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</thead>
<tbody>
<tr>
<td>Ingredient Name</td>
</tr>
<tr>
<td>Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)</td>
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<table>
<thead>
<tr>
<th>Inactive Ingredients</th>
</tr>
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<tbody>
<tr>
<td>Ingredient Name</td>
</tr>
<tr>
<td>carnauba wax (UNII: R12CBM0EIZ)</td>
</tr>
<tr>
<td>hydroxyethyl cellulose (140 mpa.s at 5%) (UNII: 8136Y38GY5)</td>
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<tr>
<td>hypromellose, unspecified (UNII: 3NXW29V3WO)</td>
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<tr>
<td>magnesium stearate (UNII: 70097M6E80)</td>
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<td>microcrystalline cellulose (UNII: OPIR32D61U)</td>
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<td>povidone, unspecified (UNII: FZ989GH04E)</td>
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<td>powdered cellulose (UNII: SMD1X3XO9M)</td>
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sodium starch glycolate type a potato (UNII: 5856J3G2A2)
titanium dioxide (UNII: 15FIX9V2JP)
triacetin (UNII: XHX3C3X673)

### Product Characteristics

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<th>Size</th>
<th>Imprint Code</th>
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<td>TYLENOL;ER</td>
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### Packaging

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<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
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<td>NDC:50580-783-10</td>
<td>1 in 1 CARTON</td>
<td>07/13/2015</td>
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<tr>
<td>2</td>
<td>NDC:50580-783-24</td>
<td>1 in 1 CARTON</td>
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<td>NDC:50580-783-25</td>
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<td>290 in 1 BOTTLE; Type 0: Not a Combination Product</td>
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<td>08/26/2019</td>
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### Marketing Information

<table>
<thead>
<tr>
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<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>07/13/2015</td>
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**Labeler** - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 3/2020