



150% ACTUAL SIZE - FOR REVIEW ONLY



ACTUAL SIZE



See New Warning NDC 5050-715-11

TYLENOL® 8HR

ARTHRITIS PAIN

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



Distributed by:
 McNeil Consumer Healthcare
 Division of McNE L-PPC, Inc.
 Fort Washington, PA 19034 USA
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Caplets
*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®" 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:
 - minor pain of arthritis
 - backache
 - premenstrual and menstrual cramps
 - the common cold
 - headache
 - toothache
- temporarily reduces fever

COVER, PAGE 1

<p>Drug Facts (continued)</p> <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> ■ 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 <p>Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> ■ skin reddening ■ blisters ■ rash <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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 	<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have liver disease</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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 <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p>
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BACK OF COVER, PAGE 2

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LOT:

EXP:

<p>Drug Facts (continued)</p> <p>Directions</p> <p>do not take more than directed (see overdose warning)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; padding: 2px;">adults</td> <td style="padding: 2px;"> <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 </td> </tr> <tr> <td style="padding: 2px;">under 18 years of age</td> <td style="padding: 2px;"> <ul style="list-style-type: none"> ■ ask a doctor </td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> ■ 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 	adults	<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 	under 18 years of age	<ul style="list-style-type: none"> ■ ask a doctor 	<p>Drug Facts (continued)</p> <p>inactive ingredients carnauba wax, croscarmellose, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p>Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)</p> <p style="font-size: x-small;">Distributed by: McNeil Consumer Healthcare Division of McNE L-PPC, Inc. Fort Washington, PA 19034 USA ©McNE L-PPC, Inc. 2013</p> <p style="text-align: right; font-size: x-small;">Visit us at www.tylenol.com</p> <p style="text-align: center;">TYLENOL® 8 HR ARTHRITIS PAIN <i>Acetaminophen extended-release tablets</i> 100 caplets - 650 mg each</p>
adults	<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 				
under 18 years of age	<ul style="list-style-type: none"> ■ ask a doctor 				



BASE LABEL, PAGE 3

(b) (4)

Reference ID: 3466482

150% ACTUAL SIZE FOR REVIEW ONLY

ACTUAL SIZE

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See New Warning NDC 50580-783-25

Push & Turn Cap

TYLENOL® 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®** 

*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
- 5 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

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Contains No Aspirin

Visit us at www.tylenol.com or call toll-free 1-877-TYLENOL (1-877-895-3665)

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Push & Turn Cap

TYLENOL® 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®** 

*Capsule-Shaped Bi-Layer Tablets

Drug Facts (continued)

■ redness or swelling is present
These could be signs of a serious condition.

Use

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	<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 ■ ask a doctor
under 18 years of age	<ul style="list-style-type: none"> ■ 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

cananda 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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3 0045-0838-377

EXP.
 LOT:

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See New Warning NDC 50580-783-25

Push & Turn Cap

TYLENOL® 8HR

Acetaminophen extended-release tablets Pain Reliever/Fever Reducer

For The Temporary Relief Of Minor Arthritis Pain

225 CAPLETS 650 mg each **Caplets®** 

*Capsule-Shaped Bi-Layer Tablets

<p>000000000</p> <p>EXP. LOT.</p>	<p>Active ingredient (in each caplet) Acetaminophen 650 mg.....Pain reliever/fever reducer</p> <p>Purpose Pain reliever/fever reducer</p> <p>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</p> <p>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</p>	<p>◀◀◀ READ THE LABEL ▶▶▶</p>	<p>professional be 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.</p> <p>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</p> <p>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</p> <p>Inactive ingredients calcium naubawax, corn starch, hydroxyethylcellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p>Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect) Distributed by: McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Fort Washington, PA 19034 USA ©McNEIL-PPC, INC. 2013</p>
	<p>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</p> <p>NDC 50580-783-25</p> <p>TYLENOL® 8HR</p> <p>ARTHRITIS PAIN</p> <p>Acetaminophen extended-release tablets Pain Reliever/Fever Reducer</p> <p>For The Temporary Relief Of Minor Arthritis Pain</p> <p>225 CAPLETS 650 mg each</p> <p>Caplets* Capsule-Shaped Bi-Layer Tablets</p>	<p>Visit us at www.tylenol.com</p>	

(b) (4)

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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, polydome, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?
call 1-877-895-3665 (toll-free) or 215-373-8755 (collect)

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NDC 50580-783-29

Push & Turn Cap

See New Warning

TYLENOL® 8HR

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

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NDC 50580-783-29

Push & Turn Cap

See New Warning

TYLENOL® 8HR

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



Caplets®
*Capsule-Shaped Bi-Layer Tablets

290 CAPLETS 650 mg each

Push & Turn Cap

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Visit us at www.tylenol.com or call toll-free 1-877-TYLENOL (1-877-895-3665)

Contains No Aspirin

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3 0045-0838-29 2



Drug Facts

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

Purpose

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 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
- 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

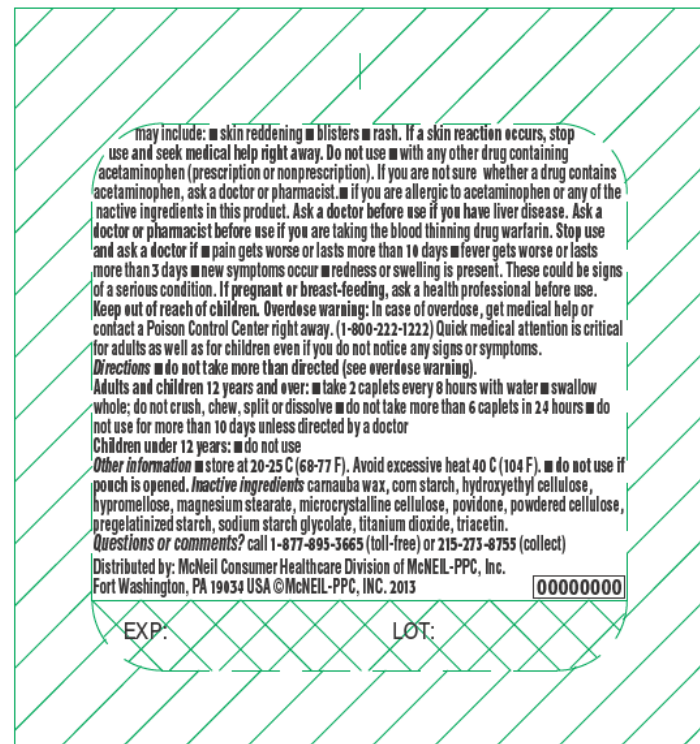
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<p>Active ingredient (in each caplet) Purpose Acetaminophen 650 mg.....Pain reliever/fever reducer</p>	<p>◀◀◀ READ THE LABEL ▶▶▶</p>	<p>These could be signs of a serious condition. If pregnant or breast-feeding, ask a health professional before use.</p>
<p>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</p>	<p style="text-align: center;">DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</p> <p style="text-align: center;">NDC 50580-783-29</p> <p style="text-align: center;">TYLENOL[®] 8HR</p> <p style="text-align: center;">ARTHRITIS PAIN</p> <p style="text-align: center;"><i>Acetaminophen extended-release tablets</i> Pain Reliever/Fever Reducer</p> <p style="text-align: center;"><i>For The Temporary Relief Of Minor Arthritis Pain</i></p>	<p>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.</p>
<p>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</p>		<p>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</p>
<p>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.</p>	<p style="text-align: center;">290 CAPLETS 650 mg each</p> <p style="text-align: center;">Caplets* *Capsule-Shaped Bi-Layer Tablets</p>	<p>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</p>
<p>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</p>		<p>Inactive ingredients carnauba wax, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p>Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect) Distributed by: McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Fort Washington, PA 19034 USA ©McNEIL-PPC, INC. 2013 Visit us at www.tylenol.com</p>

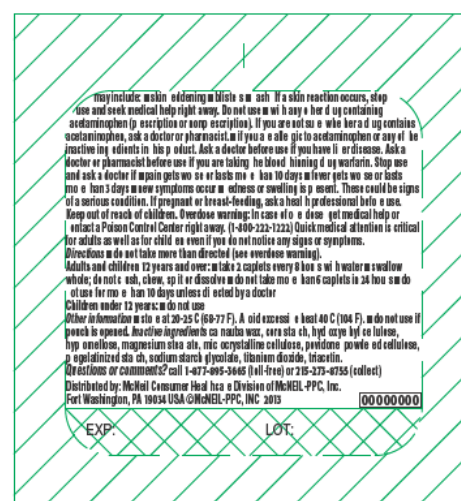
(b) (4)



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

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
 - backache
 - headache
 - minor pain of arthritis
- temporarily reduces fever

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 Fort Washington, PA 19034 USA
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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 nprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pha macist.
- if you are alle gic 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 hea th professiona before use.
Keep out of reach of children.

Overdose warning: In case of overdose, 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.

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	children under 12 years
<ul style="list-style-type: none"> ■ take 2 caplets every 8 hours w th 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 	<ul style="list-style-type: none"> ■ 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

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)

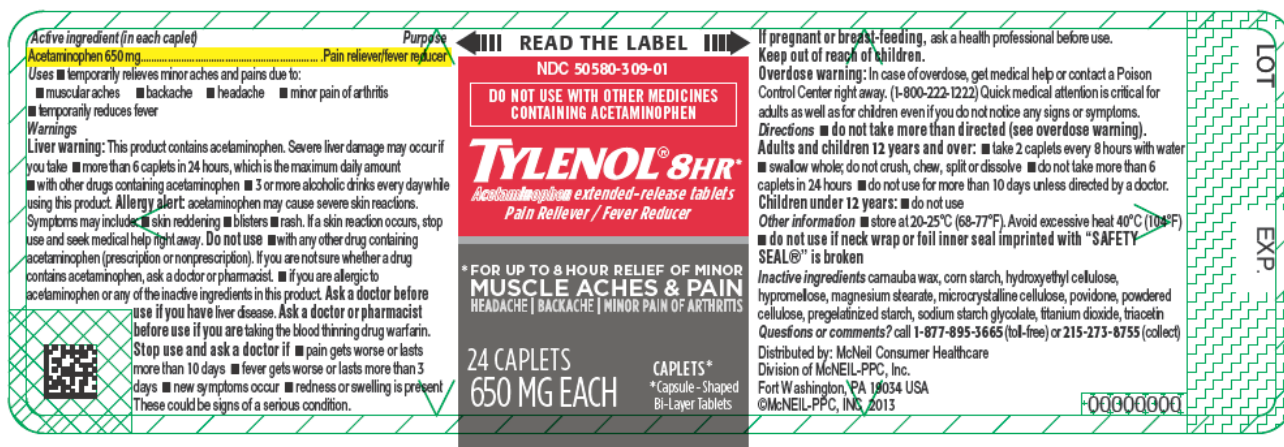
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TYLENOL[®] 8 HR
 Acetaminophen extended-release tablets
 100 caplets - 650 mg each

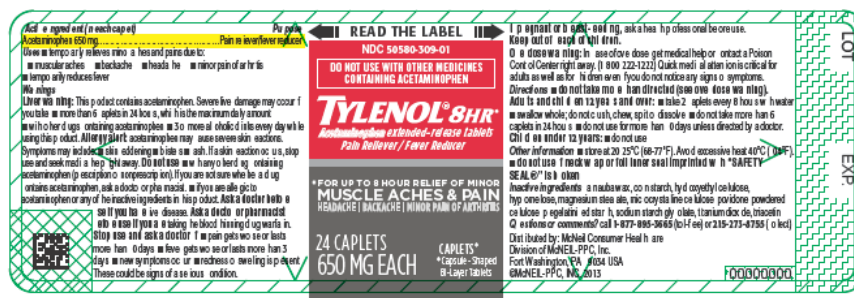
BASE LABEL, PAGE 3




(b) (4)



150% ACTUAL SIZE FOR REVIEW ONLY



ACTUAL SIZE



Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.

Overdose warning: In cases 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)

<p>adults and children 12 years and over</p> <ul style="list-style-type: none"> ■ take 2 caplets every 8 hours with water or dissolve ■ do not take more than 6 caplets in 24 hours unless directed by a doctor 	<p>children under 12 years</p> <ul style="list-style-type: none"> ■ do not use
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Other information

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

Inactive ingredients: carmelum xanthan gum, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polydioxane, polyethylene glycol, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?
 call 1-877-895-5655 (ask-tell) or 215-273-8795 (colled)

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NDC 50580-309-03

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



225 CAPLETS
650 MG EACH

CAPLETS^{*}
*Capsule - Shaped Bi-Layer Tablets

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NDC 50580-309-03

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



225 CAPLETS
650 MG EACH

CAPLETS^{*}
*Capsule - Shaped Bi-Layer Tablets

EXP. DATE
LOT



3 0045-0000-00 2

TYLENOL[®] 8HR^{*}
*Acetaminophen extended-release tablets
 Pain Reliever / Fever Reducer*

225 CAPLETS
650 MG EACH

CAPLETS^{*}
*Capsule - Shaped Bi-Layer Tablets

Contains No Aspirin

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 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 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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<p>Active ingredient (in each caplet) Acetaminophen 650 mg.....Pain reliever/fever reducer</p> <p>Purpose Pain reliever/fever reducer</p> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ muscular aches ■ backache ■ headache ■ minor pain of arthritis ■ temporarily reduces fever <p>Warnings</p> <p>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. 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 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.</p>	<p>READ THE LABEL</p> <p>NDC 50580-309-03</p> <p>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</p> <p>TYLENOL® 8HR <i>Acetaminophen extended-release tablets</i> Pain Reliever / Fever Reducer</p> <p>*FOR UP TO 8 HOUR RELIEF OF MINOR MUSCLE ACHES & PAIN HEADACHE BACKACHE MINOR PAIN OF ARTHRITIS</p> <p>225 CAPLETS 650 MG EACH</p>  <p>CAPLETS* *Capsule - Shaped Bi-Layer Tablets</p>	<p>Keep out of reach of children.</p> <p>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.</p> <p>Directions</p> <p>do not take more than directed (see overdose warning)</p> <p>Adults and children 12 years and over:</p> <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 <p>Children under 12 years:</p> <ul style="list-style-type: none"> ■ do not use <p>Other information</p> <ul style="list-style-type: none"> ■ 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 <p>Inactive ingredients carnauba wax, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p>Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)</p> <p>Distributed by: McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Fort Washington, PA 19034 USA ©McNEIL-PPC, INC. 2013</p>
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