

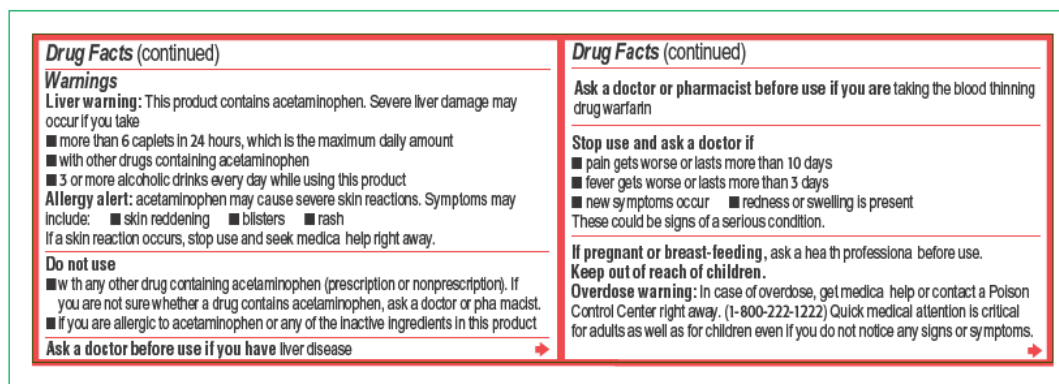


Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic				
Drug Facts: NA pt	Body Text: 4.50 pt	Bullets: 3.50 pt	Horizontal Scale: 80%	
Headers: 4.50 pt	Leading: 4.50 pt	Barlines: NA pt	Average Kerning: 0	
Subheaders: 4.50 pt	Drug Facts (cotinued): NA pt	Hairlines: NA pt		

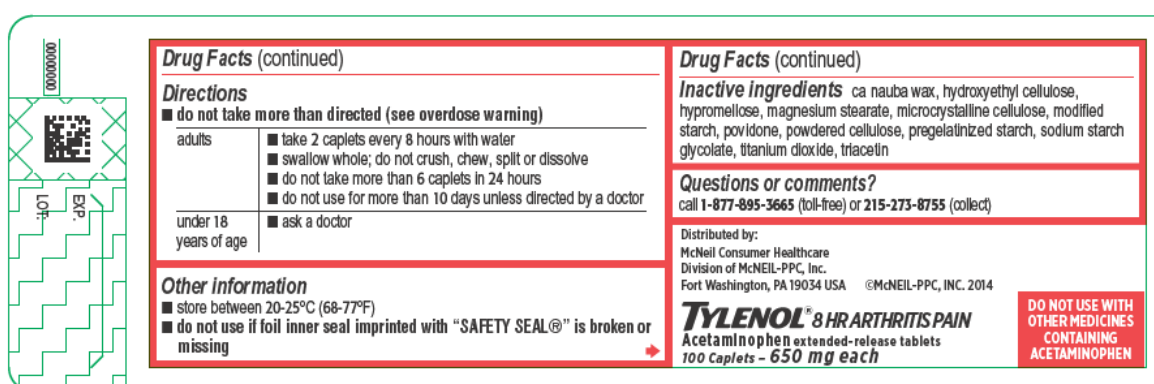
(b) (4)



COVER, PAGE 1



BACK OF COVER, PAGE 2



BASE LABEL, PAGE 3

Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic

Drug Facts: 10.00 pt	Body Text: 6.5-7.0pt	Bullets: 5.0-6.0pt	Horizontal Scale: 85%
Headers: 8.0-9.0 pt	Leading: 6.5-7.5pt	Barlines: 2.50 pt	
Subheaders: 6.0-7.0 pt	Drug Facts (continued): 9.00pt	Hairlines: 0.50 pt	Average Kerning: 0

McNeil Submission Artwork

(b) (4)

Drug Facts
Active ingredient (in each caplet) 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
- 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.

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.

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 or foil inner seal imprinted with "SAFETYSEAL" is broken

Inactive ingredients

canabua 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)



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

NDC 50580-783-25

See New Warning

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**

*Capsule-Shaped Bi-Layer Tablets

Labeling Format Information: Fonts: HelveticaDF Medium, Bold, Bold Italic

Drug Facts: 10.00 pt	Body Text: 7.00 pt	Bullets: 5.00 pt	Horizontal Scale: 85%
Headers: 9.00 pt	Leading: 7.50 pt	Barlines: 2.50 pt	
Subheaders: 7.00 pt	Drug Facts (cotinued): 9.00 pt	Hairlines: 0.50 pt	Average Kerning: 0

McNeil Submission Artwork

<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"> minor pain of arthritis muscular aches backache premenstrual and menstrual cramps the common cold headache toothache 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 use with other drugs containing acetaminophen. Do not use with 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.</p>	<p>TO OPEN: PUSH AND TURN CAP READ THE LABEL</p> <p>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</p> <p>NDC 50580-783-25</p> <p>TYLENOL 8HR ARTHRITIS PAIN</p> <p>Acetaminophen Extended-release tablets Pain Reliever / Fever Reducer</p> <p>For The Temporary Relief Of Minor Arthritis Pain</p> <p>*Capsule-Shaped Bi-Layer Tablets</p> <p>225 Caplets* 650 mg each</p>	<p>If pregnant or breast-feeding, ask a health professional before use. 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> <ul style="list-style-type: none"> 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 <p>Under 18 years of age: ask a doctor</p> <p>Other information</p> <ul style="list-style-type: none"> store between 20-25°C (68-77°F) do not use if foil inner seal imprinted with "SAFETY SEAL" is broken or missing <p>Inactive ingredients camauaba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, modified starch, 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. 2014</p>
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Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic			
Drug Facts: NA pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 90%
Headers: 8.00 pt	Leading: 6.70 pt	Barlines: NA pt	
Subheaders: 6.00 pt	Drug Facts (continued): NA pt	Hairlines: NA pt	Average Kerning: 0

McNeil Submission Artwork

(b) (4)

LOT:
EXP:

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**

*Caplet-Shaped Bi-Layer Tablets

TYLENOL[®] 8HR
ARTHRITIS PAIN

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

Contains No Aspirin

3 0045-0838-29 2

Care To Recycle[®]

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Fort Washington, PA 19034 USA
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Drug Facts (continued)

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
- ask a doctor

under 18 years of age

Other information

- store between 20-25°C (68-77°F)
- do not use if carton is opened or foil inner seal imprinted with "SAFETY SEAL" is broken

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)

Labeling Format Information: Fonts: HelveticaDF Medium, Bold, Bold Italic

Drug Facts: 10.00 pt	Body Text: 7.00 pt	Bullets: 5.00 pt	Horizontal Scale: 85%
Headers: 9.00 pt	Leading: 7.50 pt	Barlines: 2.50 pt	
Subheaders: 7.00 pt	Drug Facts (continued): 9.00 pt	Hairlines: 0.50 pt	Average Kerning: 0

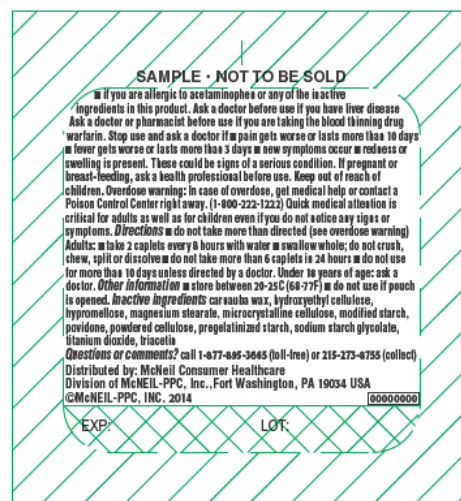
McNeil Submission Artwork

(b) (4)

<p>Active ingredient (in each caplet) Acetaminophen 650 mg.....Pain reliever/fever reducer</p>	<p>Purpose</p>	<p>TO OPEN: PUSH AND TURN CAP IIII READ THE LABEL IIII</p>	<p>■ 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>Uses</p>		<p>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</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>■ 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>NDC 50580-783-29 TYLENOL 8HR ARTHRITIS PAIN</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>Warnings</p>		<p>Acetaminophen Extended-release tablets Pain Reliever / Fever Reducer</p>	<p>Other information ■ store between 20-25°C (68-77°F) ■ do not use if foil inner seal imprinted with "SAFETY SEAL®" is broken or missing</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 ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product</p>		<p>For The Temporary Relief Of Minor Arthritis Pain</p>	<p>Inactive ingredients camauaba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, modified starch, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</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>*Capsule-Shaped Bi-Layer Tablets</p>	<p>Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)</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.</p>		<p>290 Caplets* 650 mg each</p>	<p>Distributed by: McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Fort Washington, PA 19034 USA ©McNEIL-PPC, INC. 2014</p>
<p>■ if you are allergic to acetaminophen or any of the inactive ingredients in this product</p>			
<p>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</p>			
<p>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</p>			

Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic			
Drug Facts: NA pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 90%
Headers: 8.00 pt	Leading: 7.80 pt	Barlines: NA pt	
Subheaders: 6.00 pt	Drug Facts (continued): NA pt	Hairlines: NA pt	Average Kerning: 0

McNeil Submission Artwork



Labeling Format Information: Fonts: HelveticaDF Medium, Bold, Bold Italic				
Drug Facts: NA pt	Body Text: 5.00 pt	Bullets: 4.00 pt	Horizontal Scale: 83%	
Headers: 5.50 pt	Leading: 5.25 pt	Barlines: NA pt		
Subheaders: 5.00 pt	Drug Facts (continued): NA pt	Hairlines: NA pt		

(b) (4)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
12/12/2014