

**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release  
RETAIL BUSINESS SERVICES,LLC.**

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**8 HOUR PAIN RELIEF**

**Acetaminophen Extended-Release Tablets USP, 650 mg  
Pain Reliever/Fever Reducer  
For up to 8 hours relief of Minor Muscle Aches & Pain**

**Active ingredient**

(in each caplet)

Acetaminophen USP, 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

**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**

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 of age 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 between 20-25°C (68-77°F)
- do not use if foil inner seal is broken or missing

### Inactive ingredients

hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

### Questions or comments?

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

### PDP

size	1.13/4 X 1.13/4 X 3.13/8	via	
ref #	221806048	dat	
material	016 SBS		

  

**CAREone**  
8 HOUR PAIN RELIEF

**CAREone**  
Compare to the Active Ingredient of Tylenol®  
8 Hr Musclic Aches & Pains™  
See New Warning

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

8 HOUR PAIN RELIEF

NDC 72478-186-05

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COATING FREE AREA

**Drug Facts**  
Active ingredient (in each caplet): Purpose  
Acetaminophen USP 650 mg... Pain relief/fever reducer

**Uses**  
temporarily relieve minor aches and pains due to  
muscular aches  
minor pain of arthritis  
premenstrual and menstrual cramps  
the common cold  
temporarily reduce fever

**Warnings**  
Liver warnings: This product contains acetaminophen.  
Some 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, itchy, blisters, or 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

Acetaminophen Extended-Release  
Tablets USP, 650 mg

**Pain Reliever/Fever Reducer**  
For Up to 8 Hours Relief of  
Minor Muscle Aches & Pain  
**8 Hour Muscle Aches & Pain**



**Pain Reliever/Fever Reducer**  
For Up to 8 Hours Relief of  
Minor Muscle Aches & Pain  
**8 Hour Muscle Aches & Pain**

Actual Size



**50 CAPLETS** 650 mg each  
(\*Caplets=Delayed 8-Hour Tablets)



Lot  
Exp.

**Drug Facts (continued)**

**Inactive Ingredients**

hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, pregelatinized starch, xanthan starch, hydroxypropyl methylcellulose, croscarmellose sodium, croscarmellose sodium, croscarmellose sodium

**Questions or comments?**

contact 1-877-876-8888 Mon-Fri 8:00 AM EST to 6:00 PM PST

**Contains No Aspirin**

This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8 HR Muscle Aches & Pain.

**DISTRIBUTED BY: FOODHOLD U.S.A., LLC**  
LAWSON, IN 46046  
**MADE IN INDIA**  
© 2017 Foodhold U.S.A., LLC  
Quality committed to your safety.

**This product has been tested by an independent laboratory to ensure its quality and effectiveness.**

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FREE AREA

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**Drug Facts (continued)**

**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  
May use with milk or other liquid  
If pain gets worse or lasts more than 10 days  
If fever gets worse or lasts more than 3 days  
If new symptoms occur  
If nausea or vomiting 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.

**Warnings**

Do not take more than directed (see overdose warning)  
Adults and children 12 years of age 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  
Do not use

**Other Information**

Store at room temperature (20°-25°C/68°-77°F)  
Do not use if seal break or caplets are broken or missing

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FREE AREA

code ↓ :  
 size : 213/32 X 213/32 X 413/16  
 ref # : PPL180610A  
 material : 016 SBS  
 vial # : PPL180610A  
 date : 06/01/2018

4 3/16

**CAREone**<sup>®</sup>

Compare to the Active Ingredient of Tylenol<sup>®</sup>  
 8 Hr Muscle Aches & Pain\*\*

NDC 72476-186-10

See New Warning

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

**8 HOUR PAIN RELIEF**

Acetaminophen Extended-release Tablets USP, 650 mg



**Pain Reliever/Fever Reducer**  
 For Up to 8 Hours Relief of  
 Minor Muscle Aches & Pain

Actual Size



**100 CAPLETS**<sup>®</sup> 650 mg each  
 (Capsule-Shaped 8-Layer Tablets)

**CAREone**<sup>®</sup>

**CAREone**<sup>®</sup>

Compare to the Active Ingredient of Tylenol<sup>®</sup>  
 8 Hr Muscle Aches & Pain\*\*

NDC 72476-186-10

See New Warning

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

**8 HOUR PAIN RELIEF**

Acetaminophen Extended-Release  
 Tablets USP, 650 mg

**Pain Reliever/Fever Reducer**  
 For Up to 8 Hours Relief of  
 Minor Muscle Aches & Pain



**Pain Reliever/Fever Reducer**  
 For Up to 8 Hours Relief of  
 Minor Muscle Aches & Pain

Actual Size



**100 CAPLETS**<sup>®</sup> 650 mg each  
 (Capsule-Shaped 8-Layer Tablets)

\*The product is not manufactured or distributed by Jackson Consumer Healthcare, the other of Tylenol<sup>®</sup> 8 Hr Muscle Aches & Pain.  
 \*\*Compare to the Active Ingredient of Tylenol<sup>®</sup> 8 Hr Muscle Aches & Pain.  
 ©2018 JCHH, LLC. All rights reserved. This product has been tested by an independent laboratory to verify its quality and effectiveness.  
 JCHH, LLC  
 10000 N. 10th Street, Suite 100  
 Scottsdale, AZ 85257  
 Contact your pharmacist for more information.



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**Important:** Read all product information before using. Keep the carton for important information.

Do not use if you have had a broken or missing caplet.

**Drug Facts**

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

**Uses**

- temporarily relieve minor aches and pains due to:
  - muscle aches
  - backache
  - minor pain of arthritis
  - toothache
  - premenstrual and menstrual cramps
  - headache
  - the common cold
- temporarily reduce fever

**Warnings**

- Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 caplets in 24 hours, which is the maximum daily amount.
- Do not take more than 8 caplets in 24 hours.
- Do not use for more than 10 days unless directed by a doctor.
- Always alert acetaminophen may cause severe skin reactions. Symptoms may include:
  - itching
  - hives
  - skin redness
- Do not use 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 if 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.



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Contains No Aspirin

# ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-186
<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
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

## Product Characteristics

<b>Color</b>	white (White to off white colored)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Capsule shaped, biconvex intact film coated tablets)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	G;650
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-186-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2020	
2	NDC:72476-186-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	08/19/2019	

Revised: 12/2023

RETAIL BUSINESS SERVICES,LLC.