

**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.

size : 1 1/3/4 X 1 1/3/4 X 3 1/3/8

ref # : P21506043

material : .016 SRS

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**CAREone®**

**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  
**8 Hour Muscle Aches & Pain**

**CAREone®**

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

**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  
**8 Hour Muscle Aches & Pain**

**50 CAPLETS® 650 mg each**  
(Caplets® Shaped 8H-Long Tablets)

NDC 72478-186-05

See New Warning

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**Drug Facts (continued)**

**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

**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 use with other drugs containing acetaminophen as 3 or more tablets of the every day with using the product.  
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:  
skin redness, itching, 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, 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.

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**Drug Facts (continued)**

**Ingredients in this product**

Ask a doctor before use if you have:  
Ask a doctor or pharmacist before use  
the blood thinning drug warfarin

Keep use and ask a doctor if:

- you get worse or feel more than 1
- you feel gets worse or feels more than 1
- you have signs or symptoms occur
- you have or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health

care provider before use. Keep out of reach of children.

Overdose warning: In case of overdose,

contact a Poison Control Center right away.

Quick medical attention is critical for a

child, even if you do not notice any

symptoms.

**Directions**

Do not take more than directed for

adults and children.

12 years of age and

over

in take 2 capsules

twice

in swallow whole

with or without

food. Do not take in

24 hours

in do not use for

unless directed

in do not use

children under

12 years

**Other information**

in store between 20°-25°C (68°-77°F)

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acetaminophen tablet, film coated, extended release

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-186
Route of Administration	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
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	

## Product Characteristics

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

## 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	

**Labeler** - RETAIL BUSINESS SERVICES,LLC. (967989935)