

8HR MUSCLE ACHES AND PAIN- acetaminophen tablet, film coated, extended release
CVS Pharmacy

CVS Pharmacy, Inc. 8HR Muscle Aches & 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:
- muscular aches
- backache
- minor pain of arthritis
- toothache
- premenstrual and menstrual cramps
- headache
- the common cold
- 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 and children 12 years and over	<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
children under 12 years	<ul style="list-style-type: none">• do not use

Other information

- store at 20-25°C (68-77°F)
- **do not use if printed foil under cap is broken or missing**
- meets the requirements of USP Dissolution Test 2

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient in Tylenol® 8HR

Caplets†

8HR Muscle Aches & Pain

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg

Pain Reliever/Fever Reducer

For up to 8 hours relief of minor muscle aches & pain

100 CAPLETS†, 650 mg EACH

†CAPSULE-SHAPED TABLETS

Actual Size



Compare to the active ingredient in Tylenol® 8HR*
Caplets†

NDC 69042-764-78

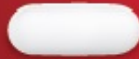
8HR Muscle Aches & Pain

ACETAMINOPHEN
EXTENDED-RELEASE TABLETS, 650 mg

Pain Reliever/Fever Reducer

For up to 8 hours relief of minor muscle aches & pain

100 CAPLETS†, 650 mg EACH
CAPSULE-SHAPED TABLETS



Actual Size



Package Contains One Bottle

Actual Size



8HR Muscle Aches & Pain

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg

Pain Reliever/Fever Reducer
Contains No Aspirin

Distributed by CVS Health Company, Inc.
One CVS Dr., Worcester, MA 01095
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CVS Health
Pain Relief

US Patent 8,077,212



Drug Facts

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

Uses

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 - backache
 - minor pain of arthritis
 - toothache
 - premenstrual and menstrual cramps
 - headache
 - fever on non cold
- temporarily reduces fever

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 - 3 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.

Do not use

- with any other drug containing acetaminophen (read label or prescription). 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)

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	swallow whole; do not crush, chew, split or dissolve
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children under 12 years	do not use

Other information

- store at 20-25°C (68-77°F)
- do not use if printed ball under cap is broken or missing
- meets the requirements of USP Dissolution Test 2

Inactive ingredients: carmellose, croscellose, croscellose sodium, hypromellose, magnesium stearate, methylcellulose, microcrystalline cellulose, polyethylene glycol, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 30000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000, polyethylene glycol 150000, polyethylene glycol 200000, polyethylene glycol 300000, polyethylene glycol 400000, polyethylene glycol 600000, polyethylene glycol 800000, polyethylene glycol 1000000, polyethylene glycol 1500000, polyethylene glycol 2000000, polyethylene glycol 3000000, polyethylene glycol 4000000, polyethylene glycol 6000000, polyethylene glycol 8000000, polyethylene glycol 10000000, polyethylene glycol 15000000, polyethylene glycol 20000000, polyethylene glycol 30000000, polyethylene glycol 40000000, polyethylene glycol 60000000, polyethylene glycol 80000000, polyethylene glycol 100000000, polyethylene glycol 150000000, polyethylene glycol 200000000, polyethylene glycol 300000000, polyethylene glycol 400000000, polyethylene glycol 600000000, polyethylene glycol 800000000, polyethylene glycol 1000000000, polyethylene glycol 1500000000, polyethylene glycol 2000000000, polyethylene glycol 3000000000, polyethylene glycol 4000000000, polyethylene glycol 6000000000, polyethylene glycol 8000000000, polyethylene glycol 10000000000

Questions or comments? 1-800-779-9280

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8HR.



8HR MUSCLE ACHES AND PAIN

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-764
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L544
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69842-764-78	1 in 1 CARTON	01/09/2020	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	01/09/2020	

Labeler - CVS Pharmacy (062312574)

Revised: 1/2020

CVS Pharmacy