# ACETAMINOPHEN REGULAR STRENGTH- acetaminophen tablet, coated CVS PHARMACY

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## CVS 44-678-Acetaminophen

## Active ingredient (in each gelcap)

Acetaminophen 325 mg

## **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - backache
  - minor pain of arthritis
  - toothache
  - muscular aches
  - premenstrual and menstrual cramps
- temporarily reduces fever

## Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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.

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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
- adults and children 12 years and over
  - take 2 gelcaps every 4 to 6 hours while symptoms last
  - do not take more than 10 gelcaps in 24 hours, unless directed by a doctor
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- use by expiration date on package

## Inactive ingredients

corn starch, croscarmellose sodium, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, propylene glycol, shellac glaze, stearic acid, titanium dioxide

#### Questions or comments?

1-800-426-9391

## Principal display panel

#### **CVS**

Health®

Compare to the active ingredient in Tylenol® Regular Strength\*

Gelcaps

Regular Strength **Acetaminophen** Gelcaps, 325 mg

Pain reliever, Fever reducer

Aspirin Free

**Actual Size** 

**365** GELCAPS

## TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® Regular Strength. 50844 REV0421A67851

# Distributed by: CVS Pharmacy, Inc.

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Directions

do not take more than directed

adults and children 12 years and over

adults and children 16 years and over

take 2 getcaps every 4 to 6 hours while symptoms last

do not take more than 10 getcaps in 24 hours, unless directed by a If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice Inactive ingredients corn starch, croscarmellose sodium, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron propylene glycol, shellac glaze, stearic acid oxide black, iron oxide any signs or symptoms new symptoms occur ■ pain gets worse or lasts more than 10 days
■ fever gets worse or lasts more than 3 days Stop use and ask a doctor if Ask a doctor or pharmacist before use if you are taking the blood thinning Ask a doctor before use if you have liver disease Drug Facts (continued) store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) redness or swelling is present fnese could be signs of a serious condition. Luestions or comments? 1-800-426-9391 children under 12 years: ask a doctor do not take for more than 10 days unless directed by a doctor expiration date on package STOP PEELING , IO glycol, povidone

#### CVS 44-678

## **ACETAMINOPHEN REGULAR STRENGTH**

acetaminophen tablet, coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-876
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients		
Ingredie	ent Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)		

CROSCARMELLOSE SODIUM (UNII: M280L1HH48)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
FERROSOFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX43802MRT)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHELLAC (UNII: 46N107B710)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics				
Color	red, white	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	LB	
Contains				

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:69842- 876-51	365 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/24/2015		

Marketing Information					
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M013	07/24/2015			

## Labeler - CVS PHARMACY (062312574)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(69842-876) , pack(69842-876)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(69842-876)

## **Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(69842-876)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(69842-876)

Revised: 11/2023 CVS PHARMACY