ACETAMINOPHEN- acetaminophen capsule, liquid filled CVS Pharmacy

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CVS 44-718

Active ingredient (in each liquid-filled capsule)

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 (1-800-222-1222) 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 capsules every 4 to 6 hours while symptoms last
 - do not take more than 10 capsules 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)
- protect from heat, humidity and light
- see end flap for expiration date and lot number

Inactive ingredients

edible white ink, FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

Questions or comments?

1-800-426-9391

Principal display panel

CVSHealth_{TM}

Compare to the active ingredient in Tylenol® Regular Strength*

Liquid-Filled Gels

Regular Strength

Acetaminophen

325 mg, Liquid Gels

Pain reliever, Fever reducer

Aspirin free

Package Contains One Bottle

20 LIQUID-FILLED GELS

Actual Product Size and Shape on Side Panel

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® Regular Strength. 50844 ORG011971809

Distributed by: CVS Pharmacy, Inc.

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Product of India V-11112

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



CVS Health 44-718

ACETAMINOPHEN

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-918 Route of Administration ORAL Active Ingredient/Active Moiety

Basis of Strength

Strength

Ingredient Name

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | |
| GELATIN (UNII: 2G86QN327L) | | | |
| GLYCERIN (UNII: PDC6 A3C0 OX) | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | |
| PO VIDO NE (UNII: FZ989 GH94E) | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| SORBITOL (UNII: 506T60A25R) | | | |

| Product Characteristics | | | | |
|-------------------------|-------------|--------------|----------|--|
| Color | RED (clear) | Score | no score | |
| Shape | OVAL | Size | 15mm | |
| Flavor | | Imprint Code | 718 | |
| Contains | | | | |

| F | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:69842-918- 09 | 1 in 1 CARTON | 0 4/15/20 19 | | |
| 1 | | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC MONOGRAPH NOT FINAL | part343 | 04/15/2019 | | |
| | | | | |

Labeler - CVS Pharmacy (062312574)

| Establishment | | | | |
|-------------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| LNK International, Inc. | | 038154464 | PACK(69842-918) | |

Revised: 3/2020 CVS Pharmacy