

LEADER ACETAMINOPHEN- acetaminophen tablet
Praxis, LLC

Cardinal Health Acetaminophen Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- the common cold
- headache
- 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 have ever had an allergic reaction to this product or any of its ingredients

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 6 hours while symptoms last• do not take more than 6 caplets in 24 hours, unless directed by a doctor• do not use for more than 10 days unless directed by a doctor |
| children under 12 years | ask a doctor |

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

carnauba wax, corn starch*, croscarmellose sodium*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid *may contain one or more of these ingredients

Questions or comments?

1-800-719-9260

Principal Display Panel

LEADER™

Extra Strength

Acetaminophen Caplets, 500 mg

Pain Reliever / Fever Reducer

COMPARE TO EXTRA STRENGTH TYLENOL® CAPLETS active ingredient

For Adults

100% Money Back Guarantee

Actual Size

24 CAPLETS



LEADER ACETAMINOPHEN

acetaminophen tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59368-228 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 500 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 16mm |
| Flavor | | Imprint Code | L484 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59368-228-03 | 1 in 1 CARTON | 08/13/2018 | |
| 1 | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:59368-228-01 | 1 in 1 CARTON | 08/13/2018 | |
| 2 | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:59368-228-02 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 08/13/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013 | 08/13/2018 | |

Labeler - Praxis, LLC (016329513)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|---|
| Praxis, LLC | | 016329513 | label(59368-228) , manufacture(59368-228) , pack(59368-228) |