

HEALTHY ACCENTS PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet
DZA Brands LLC

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.

DZA Brands, LLC Pain Relief 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?

1-866-322-2439

Principal Display Panel

Compare to Extra Strength Tylenol® Caplets active ingredient

SEE NEW WARNINGS

extra strength

pain relief

acetaminophen

pain reliever – fever reducer

for adults – gluten free

actual size

50 caplets – 500mg each





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EXP.

LOT NO.



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■ 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

Drug Facts (continued)

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Drug Facts (continued)

Questions or comments?

1-866-322-2439

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY: DZA BRANDS, LLC
Asbury, NC 28147
Dorchester, ME 04074
For product questions or concerns,
contact us at 1-866-322-2439.
These include UPC number
and code from package.



HEALTHY ACCENTS PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55316-484 |
| 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) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| POVIDONES (UNII: FZ989GH94E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |

Product Characteristics

| | | | |
|----------|------------------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | CAPSULE (caplet) | Size | 16mm |
| Flavor | | Imprint Code | L484 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:55316-484-71 | 1 in 1 CARTON | | |
| 1 | | 50 in 1 BOTTLE | | |
| 2 | NDC:55316-484-78 | 1 in 1 CARTON | | |
| 2 | | 100 in 1 BOTTLE | | |
| 3 | NDC:55316-484-90 | 500 in 1 BOTTLE | | |
| 4 | NDC:55316-484-62 | 1 in 1 CARTON | | |
| 4 | | 24 in 1 BOTTLE | | |
| 5 | NDC:55316-484-76 | 1 in 1 CARTON | | |
| 5 | | 120 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 02/04/2008 | |

Labeler - DZA Brands LLC (090322194)

Revised: 1/2015

DZA Brands LLC