

COUNTERACT PAIN- acetaminophen tablet, film coated
Melaleuca, Inc.

CounterAct Pain Content of Labeling

Active Ingredients (in each caplet)

Acetaminophen 500 mg

Purposes

Pain Reliever/fever reducer

Uses

- for the temporary relief of 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 8 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

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.

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: Taking more than the recommended dose (overdose) may cause liver damage. 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
 - take 2 caplets every 4 to 6 hours while symptoms last
 - do not take more than 8 caplets in 24 hours
 - do not take more than 10 days unless directed by a doctor
- children under 12 years: do not use this adult extra strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage

Other information

- store at room temperature

Inactive ingredients Hypromellose, Polyethylene Glycol, Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid.

Questions or comments? If you have any questions or comments, or to report and adverse event, please contact **1-800-282-3000**.

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

Drug Facts (continued)


Directions **do not take more than directed** (see previous warnings)

- in adults and children 12 years and over
 - in take 2 caplets every 4 to 6 hours while symptoms last
 - in do not take more than 8 caplets in 24 hours
 - in do not take for more than 10 days unless directed by a doctor
- in children under 12 years: do not use this adult extra-strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage

Other information


- in store at controlled room temperature 15°-30°C (59°-86°F)
- in use by expiration date on package

Dist by: Melaleuca, Inc.
 Idaho Falls, ID 83402
 Tel order: 1-800-282-5000
 Melaleuca.com #2251 11/15 U



Melaleuca
 EXTRA-STRENGTH
CounterAct Pain
 Acetaminophen
 Pain Reliever/Fever Reducer
 Safe, Fast Pain & Fever Relief
 without Aspirin

50 Caplets
 500 mg each



RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each caplet) **Purpose**
 Acetaminophen 500 mg.....Pain reliever/fever reducer

Uses

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

Warnings See carton for complete 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, which is the maximum daily amount in with other drugs containing acetaminophen in 3 or more alcoholic drinks every day while using this product in do not take for pain for more than 10 days in do not take for fever for more than 3 days unless directed by a doctor

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.


Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Drug Facts (continued on back)

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

Rev. 11/15







Lot #
 Exp.



Melaleuca
 The Wellness Company

Artwork Information

| | |
|-------------------------------------|--|
| 1. File name and Revision Date: | 108002251_CounterAct Pain Label_11/15U_o.pdf |
| 2. Part Number: | 108002251 |
| 3. Color: Process, PMS (up to 7): | CMYK |
| 4. Label size: | 4.625 x 1.5 |
| 5. Format: | Adobe Illustrator CS5 |
| 6. Artwork contact. Name & Phone #: | Corban Lindsay 208-522-0700 x2263 |

| | | | | | |
|---|---|---|---|---|---|
|  |  |  |  |  |  |
| CMYK | Pantone 165 | Pantone 012 C | Process Black | Deadner | Dieline |



acetaminophen tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54473-305 |
| 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 |
|---|-----------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|-----------------|------------------|---------------------|----------|
| Color | white (White) | Score | no score |
| Shape | CAPSULE (Caplet) | Size | 18mm |
| Flavor | | Imprint Code | None |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:54473-305-50 | 1 in 1 BOX | 01/01/2018 | |
| 1 | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug | M013 | 05/02/2016 | |

Labeler - Melaleuca, Inc. (139760102)

