

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

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.

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 overdose warnings)
- adults and children 12 years and over
 - take 2 caplets every 4 to 8 hours while symptoms last
 - do not take more than 8 caplets in 24 hours
 - do not take for 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 controlled room temperature 15°–30°C (59°–86°F)
- use by expiration date on package

Dist by: Melaleuca, Inc.
 Irvine Falls, ID 83432
 To order: 1-800-282-3000
 Melaleuca.com #225111/15 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

- temporarily relieves minor aches and pains due to:
 - headache
 - backache
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
 - 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. If you take more than 3,000 mg of acetaminophen in 24 hours, which is the maximum daily amount, with other drugs containing acetaminophen, or 3 or more alcoholic drinks every day while using this product, you do not take for pain for more than 10 days, or 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.

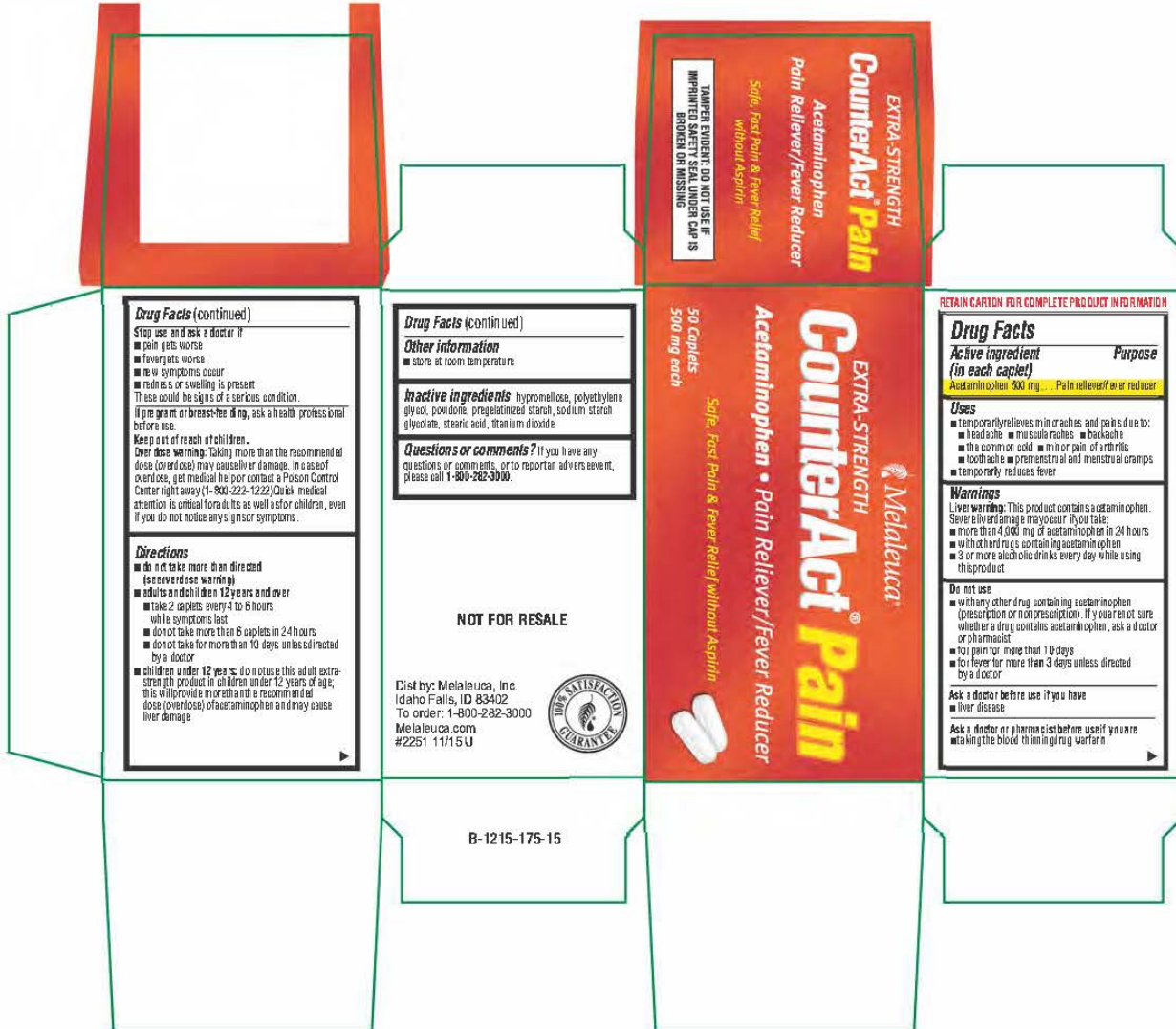


Melaleuca
 The Wellness Company

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



Drug Facts (continued)
 Stop use and ask a doctor if:
 ■ pain gets worse
 ■ fever gets worse
 ■ new symptoms occur
 ■ redness or swelling is present
 These could be signs of a serious condition.
 If pregnant or breastfeeding, ask a health professional before use.
 Keep out of reach of children.
Over dose warning: Taking more than the recommended dose (over dose) may cause liver damage. In case of over dose, 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 over dose warning)
 ■ adults and children 12 years and over
 ■ take 2 capsules every 4 to 6 hours while symptoms last
 ■ do not take more than 6 capsules in 24 hours
 ■ do not take for 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 a recommended dose (over dose) of acetaminophen and may cause liver damage

Drug Facts (continued)
Other information
 ■ store at room temperature

Inactive ingredients hyponellase, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

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

NOT FOR RESALE

Dist by: Melaleuca, Inc.
 Idaho Falls, ID 83402
 To order: 1-800-282-3000
 Melaleuca.com
 #2251 11/15 U



EXTRA-STRENGTH
CounterActi Pain
 Melaleuca
 Acetaminophen • Pain Reliever/Fever Reducer
 Safe, Fast Pain & Fever Relief without Aspirin
 50 Capsules
 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
 ■ temporarily relieves minor aches and pains due to:
 ■ headache ■ muscle aches ■ backache
 ■ the common cold ■ minor pain of arthritis
 ■ toothache ■ 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

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
 ■ for pain for more than 10 days
 ■ for fever for more than 3 days unless directed by a doctor

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

B-1215-175-15

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 not final	part343	05/02/2016	

Labeler - Melaleuca, Inc. (139760102)

