COUNTERACT PM- acetaminophen and diphenhydramine tablet
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 PM Content of Label

Active ingredients

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

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.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age
- if you are allergic to acetaminophen or any of the ingredients in this product

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 maimum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- drowsiness will occur
- avoid alcoholic beverages
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a searious underlying medical illness.
- new symptoms occur
- redness or swelling is present
- pain gets worse of lasts more than 10 days
- fever gets worse or lasts more than 3 days

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.

Keep out of reach of children

Purpose

Pain reliever

Nighttime sleep-aid

Directions

do not take more than directed (see overdose warning)
adults and children 12 years and over: take 2 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours.
children under 12 years: do not use.

Other Information

- store at controlled room temperature 15-30 ºC (59-86 ºF)
- see end flap for expiration date and lot number

Questions or comments?

If you have any questions or comments, or to report an adverse even, please contact 1-800-282-3000.

Inactive ingredients

calcium carbonate, corn starch, citric acid, croscarmellose sodium, hypromellose, lactose, magnesium silicate,

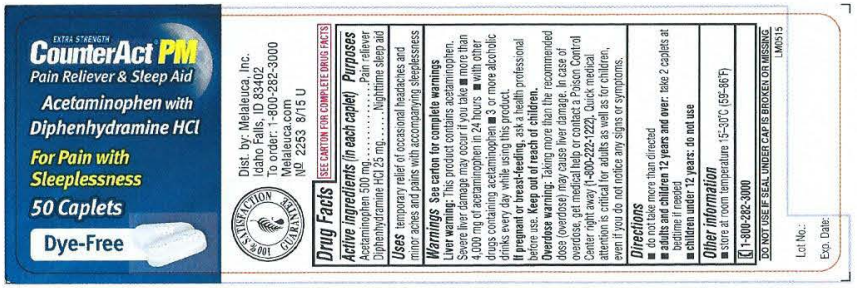
magnesium stearate, maltodextrin, microcrystalline cellulose, medium-chain triglyceride, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, sodium carbonate, sodium starch glycolate, stearic acid.

Do not take this product unless directed by a doctor if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- liver disease
- a breathing problem such as emphysema or chronic bronchitis

Uses

temporary relief of occassional headaches, minor aches, and pains with accompanying sleeplessness



Melaleuca Artwork Information

1. File name and Revision Date:	101302253_CounterActPM_Bottle_04/15_U_0.pdf
2. Part Number:	101302253
3. Color: Process, PMS (up to 8):	see box below
4. Label size:	see die
5. Format:	Illustrator CC
6. Artwork contact. Name & Phone #:	Corban Lindsay 208-522-0700 x2109

Reflex Blue

Pantone 485

Pantone 108

4-color process

DIE LINE

NOT TO BE PRINTED AS ARTWORK.

Melaleuca The Wellness Company — Artwork Information

1. File name and Revision Date:	101302253_CounterActPM_Box_04/15_U_0.pdf
2. Part Number:	101302253
3. Color: Process, PMS (up to 8):	see box below
4. Label size:	see die
5. Format:	Illustrator CC
6. Artwork contact. Name & Phone #:	Corban Lindsay 208-522-0700 x2109

Reflex Blue

Pantone 485

Pantone 108

4-color process

DIE LINE

NOT TO BE PRINTED AS ARTWORK

COUNTERACT PM

acetaminophen and diphenhydramine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54473-304
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PYRROLIDONE (UNII: KKL5D39EOL)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white (no color added)	**Score**	no score
Shape	CAPSULE (Caplet)	**Size**	18mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-304-01	1 in 1 BOX	05/02/2016	
1	NDC:54473-304-50	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)

Registrant - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical		078301063	manufacture(54473-304)

Revised: 1/2019 Melaleuca, Inc.