

**HEALTHY MAMA EAZZE THE PAIN- acetaminophen diphenhydramine
hydrochloride tablet, film coated
MATERNAL SCIENCE, 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.

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25mg

Purposes

Pain Reliever Nighttime Sleep Aid

Uses

Temporary relief of occasional headaches and minor aches with pains with accompanying sleeplessness.

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 everyday while using this product

When using this product

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

Keep out of reach of children.

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.
- In children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you are

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

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

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- 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.

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 at bedtime. Do not take more than 2 caplets of this product in 24 hours

Children under 12 years: Do not use this adult product in children under 12 years of age: this will provide more than the recommended dose(overdose) and may cause liver damage.

Other information

- Store at room temperature

Inactive ingredients

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid.

Questions?

If you have any questions or comments. or to report an adverse event, please contact (xxx) xxx-xxxx.

Principal Display Panel

healthy

mama

eaZZZe THE PAIN!

acetaminophen 500mg diphenhydramine HCl 25 mg

PAIN RELIEVER AND NIGHTTIME AID

extra strength aspirin free

40 caplets

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Diphenhydramine HCl 25 mg.....	Nighttime Sleep Aid
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Ask a doctor before use if you have • liver disease • a breathing problem such as emphysema or chronic bronchitis • difficulty in urination due to enlargement of the prostate gland • glaucoma	
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 drinks • do not drive a motor vehicle or operate machinery	

Rev. XX/XX

Drug Facts (continued on back)

Do not use if imprinted seal under cap is broken or missing

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PAIN RELIEVER AND NIGHTTIME SLEEP AID
extra strength • aspirin free
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Lot# Exp.
SEE THE SEAL

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Inactive ingredients Croscarmellose Sodium, Crospovidone, FD&C Blue #1, Hydroxypropyl Cellulose, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Pregelatinized Starch, Propylene Glycol, Silica, Sodium Starch Glycolate, Stearic Acid and Titanium Dioxide.

Questions? If you have any questions or comments, or to report an adverse event, please contact (XXX) XXX-XXXX.

HEALTHY MAMA EAZZE THE PAIN

acetaminophen diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 154-104
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 68401960MK)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (Capsule shaped tablet)	Size	18mm
Flavor		Imprint Code	GP325
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58154-104-01	40 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/29/2013	

Labeler - MATERNAL SCIENCE, LLC (078722406)

Revised: 4/2013

MATERNAL SCIENCE, LLC