

TENSION HEADACHE RELIEF- acetaminophen 500mg tablet, coated
Healthlife of USA

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.

Tension Headache Relief

Drug Facts

Tension Headache Relief

Purpose

Pain reliever, Pain reliever aid

Active Ingredients (in each caplet)

Acetaminophen 500mg

Caffeine 65mg

Uses

Temporarily relief minor aches and pains due to:

- Headache
- Muscular aches

Warnings

Liver warning: This product contains acetaminophen. severe liver damage may occur if you take:

- more than 6 tablets 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

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally rapid heartbeat.

Do not Use

- with any other drug containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.

Ask a doctor before use

- if you have liver disease

Ask a doctor or pharmacist

If you are taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- Any new symptoms appear
- Symptoms do not get better or worsen
- Painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 exceed recommended dosage.
- Adults and children 12 years and over: Take 2 tablets every 6 hours; do not take more than 6 tablets in 24 hours
- Children under 12 years: Ask a doctor

Other Information

- Store at controlled room temperature 20°-25°C (68°-77°F)
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP

Inactive Ingredients

- Colloidal silicon dioxide
- Croscarmellose sodium
- D&C red # 27
- FD&C blue # 1
- FD&C yellow # 6
- Magnesium stearate
- Microcrystalline cellulose
- Polyethylene glycol
- Pregelatinized starch
- Polyvinyl pyrolidone
- Stearic acid
- Talc
- Titanium dioxide

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM EST or www.healthlifeofusa.com

Tension Headache Relief

Acetaminophen 500mg

Caffeine 65mg

24 Caplets Compare to Excedrin® Tension Headache active ingredients Distributed by:
 Healthlife of USA LLC
 Rahway
 NJ 07065
 www.healthlifeofusa.com



TENSION HEADACHE RELIEF			
acetaminophen 500mg tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-118

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-118-24	1 in 1 CARTON	05/31/2017	
1		24 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	05/31/2017	

Labeler - Healthlife of USA (079656178)**Establishment**

Name	Address	ID/FEI	Business Operations
Healthlife of USA		079656178	repack(69517-118)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Limited		915664486	manufacture(69517-118) , pack(69517-118)

Revised: 6/2017

Healthlife of USA