DRX CHOICE TENSION HEADACHE- acetaminophen, caffeine tablet, film coated

Raritan Pharmaceuticals Inc.

DRx Choice Tension Headache relief Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg Caffeine 65 mg

Purposes

Pain reliever

Pain reliever aid

Uses

- temporarily relieves minor aches and pain due to:
- headache
- muscular aches

Warnings

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Liver warning:

- This product contains acetaminophen. Severe liver damage may occur if you take
- more than 6 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

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

- if you are allergic to acetaminophen
- 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

- any new symptoms occur
- 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

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.

In case of overdose, get medical help or contact a Poison Control Center right away at 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 use more than directed
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 6 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at room temperature
- close cap tightly after use
- read all product information before using.

Inactive ingredients

Colloidal silicon dioxide, croscarmellose sodium, D&C red no. 27, FD&C blue no. 2, FD&C yellow no. 6, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyvinyl pyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-866-467-2748

Principal Display Panel

Compare to Excedrin® Tension Headacheactive ingredients *

NDC 68163-506-15

DRx Choice

tension headache

relief

ASPIRIN-FREE

Acetaminophen 500 mg, Caffeine 65 mg

Pain Reliever / Pain Reliever Aid

ACTUAL SIZE

15 CAPLETS

TAMPER-EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS BROKEN OR MISSING.

IMPORTANT:Keep this carton for future reference on full labeling.

Distributed by: Raritan Pharmaceuticals

8 Joanna Court

East Brunswick, NJ 08816

*This product is not manufactured or distributed by Haleon CH Sarl., owner of the registered trademark Excedrin Tension Headache.



DRX CHOICE TENSION HEADACHE

acetaminophen, caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-506
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	red	Score	no score
Shape	OVAL (Caplet)	Size	17mm
Flavor		Imprint Code	RP065
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-506- 15	1 in 1 CARTON	05/16/2025	
1		15 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	05/16/2025	

Labeler - Raritan Pharmaceuticals Inc. (127602287)

Revised: 6/2025 Raritan Pharmaceuticals Inc.