ASPIRIN-FREE TENSION HEADACHE- acetaminophen and caffeine capsule Rite Aid

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.

Rite Aid 44-428

Active ingredients (in each caplet)

Acetaminophen 500 mg (formulated with 65 mg caffeine)

Purpose

Pain reliever

Uses

- temporarily relieves 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 8 caplets in 24 hours, which is the maxiumum 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). 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

- new symptoms appear
- symptoms do not get better or worsen
- painful area is red and swollen
- pain gets worse or 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 (1-800-222-2222) 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 use more than directed (see overdose warning)
- adults and children12 years and over: take 2 caplets every 6 hours. Do not take mroe than 8 caplets in 24 hours.
- children under 12 years: do not use this 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 controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, D&C red #27 aluminum lake, FD&C #2 aluminum lake, FD&C #6 aluminium lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

RITE AID® PHARMACY

*Compare to the active ingredients in Excedrin® Tension Headache

tension headache
pain reliever
acetaminophen 500 mg
caffeine 65 mg
pain reliever • pain reliever aid
aspirin free

100 COATED CAPLETS

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Excedrin® Tension Headache.

50844 ORG081042812

Distributed by: RITE AID 30 HUNTER LANE CAMP HILL, PA 17011

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



Rite Aid 44-428

ASPIRIN-FREE TENSION HEADACHE acetaminophen, caffeine capsule Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:11822-0428 Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg	
CAFFEINE (CAFFEINE)	CAFFEINE	65 mg	

Inactive Ingredients		
Ingredient Name	Strength	
D&C RED NO. 27		
TALC		
FD&C YELLOW NO. 6		

Product Characteristics			
Color	RED	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	44;428
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:11822-0428-2	1 in 1 CARTON		
1	100 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	0 1/17/20 0 7	

Labeler - Rite Aid (014578892)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11822-0428)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(11822-0428)

Revised: 10/2012 Rite Aid