

NOTTS - TENSION HEADACHE- acetaminophen, caffeine tablet
VIVUNT PHARMA LLC

NOTTS - Tension Headache

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Caffeine 65 mg

Purpose

Pain Reliever

Pain reliever Aid

Uses

For the temporary relief of minor aches and pains due to:

- common cold
- headache
- toothache
- muscular aches
- backaches
- premenstrual and menstrual cramps
- minor pain from arthritis

Warnings

Liver Warning:

Liver warning: This product contains acetaminophen.

Severe damage may occur if you take:

- more than 4,000 mg of acetaminophen 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.

Allergy alert:

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- rash
- blisters.

If a skin reaction occurs, stop use and seek medical attention immediately

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.
- if you are allergic to acetaminophen or any of the inactive ingredients.

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

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children

Overdose warning:

Do not take more than recommended dosage. In case of overdose, get medical help or contact a Poison Control Center. Prompt 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
- Do not take more than 6 caplets in 24 hours, or as directed by a doctor

adults and children 12 years and over

- take 2 caplets every 6 hours

children under 12 years

- ask a doctor
-

Other information

- Store between 20-25 °C (68-77 °F)
- Tamper-evident: Do not use if carton is open or the foil inner seal is broken or

missing.

Inactive ingredients

Croscarmellose Sodium, D&C Red No.27 Aluminium Lake, Magnesium Stearate, Microcrystalline Cellulose, Polacrillin Potassium, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Starch, Talc.

*This product is not manufactured or distributed by GSK group of companies, owner of the registered trademark Excedrin® Tension Headache Caplets.

Distributed by: VIVUNT PHARMA LLC

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Miami, FL 33156-3178

Made in India.

www.vivunt.live

Package Principal Display Panel - TH 24 Caplets

NOTTS®

Tension Headache

500 mg 65 mg each caplet

- Headaches Relief
- Aspirin Free

Compare to Excedrin® Tension Headache active ingredients*

NDC 82706-010-01

24 CAPLETS



Package Principal Display Panel - TH 100 Caplets

NOTTS®

Tension Headache

500 mg 65 mg each caplet

Headaches Relief

Aspirin Free

Compare to Excedrin® Tension Headache active ingredients*

NDC 82706-010-02



NOTTS - TENSION HEADACHE

acetaminophen, caffeine tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:82706-010

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
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STARCH, CORN (UNII: O8232NY3S)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POVIDONE (UNII: FZ989GH94E)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	Notts;TH
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-010-01	1 in 1 CARTON	10/30/2023	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:82706-010-02	1 in 1 CARTON	10/30/2023	
2		100 in 1 BOTTLE, PLASTIC; 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	10/30/2023	

