

EXCEDRIN TENSION HEADACHE- acetaminophen, caffeine tablet, film coated
GlaxoSmithKline Consumer Healthcare Holdings (US) 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 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. 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 20°-25°C (68°-77°F)
- close cap tightly after use
- read all product information before using. Keep this box for important information.

Inactive ingredients

benzoic acid, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-452-0051

Principal Display Panel

NDC 0067-8139-02

EXCEDRIN®

TENSION HEADACHE

Acetaminophen and Caffeine

Pain Reliever / Pain Reliever Aid

Aspirin Free

100 CAPLETS

TAMPER-EVIDENT BOTTLE

DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH “SEALED for YOUR PROTECTION” IS BROKEN OR MISSING

Distributed by: **GSK Consumer Healthcare,**

Warren, NJ 07059

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NDC 0067-8139-02

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TENSION HEADACHE

Aspirin Free

Acetaminophen and Caffeine
Pain Reliever / Pain Reliever Aid

100
CAPLETS



EXCEDRIN TENSION HEADACHE

acetaminophen, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-8139
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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
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)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL ((Caplet))	Size	17mm
Flavor		Imprint Code	ETH
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8139-01	1 in 1 CARTON	12/15/2016	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0067-8139-02	1 in 1 CARTON	12/15/2016	
2		100 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	12/15/2016	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)