

**EXCEDRIN EXTRA STRENGTH AND EXCEDRIN TENSION HEADACHE- acetaminophen, aspirin (nsaid), and caffeine**

**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.*

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***Drug Facts***

**Excedrin Tension Headache**

[Enter Generic Section here]

***Active ingredients (in each caplet)***

Acetaminophen 500 mg

Caffeine 65 mg

***Purposes***

Pain reliever

Pain reliever aid

***Uses***

- temporarily relieves minor aches and pains 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 no. 27 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

## **Questions or comments?**

**1-800-468-7746**

## **Excedrin Extra Strength**

[Enter Generic Section here]

### ***Active ingredients (in each caplet)***

Acetaminophen 250 mg

Aspirin 250 mg (NSAID\*)

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

### ***Purposes***

Pain reliever

Pain reliever

Pain reliever aid

### ***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - toothache
  - premenstrual & menstrual cramps

### ***Warnings***

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**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.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives

- facial swelling
- asthma (wheezing)
- shock

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

- more than 8 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

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**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 heart beat.

#### **Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- 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
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

#### **Ask a doctor or pharmacist before use if you are taking**

- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition

#### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- painful area is red or swollen
- pain gets worse or last for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms occur

These could be signs of a serious condition

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**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**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 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, carnauba wax, FD&C blue #1, hydroxypropylcellulose, hypromellose, light mineral oil, microcrystalline cellulose, polysorbate 20, povidone, propylene glycol, simethicone emulsion, sorbitan monolaurate, stearic acid, titanium dioxide

***Questions or comments?***

**1-800-468-7746**

Principal Display Panel (Excedrin Tension Headache)

NDC 0067-8139-01

**EXCEDRIN®**

**TENSION HEADACHE**

*Acetaminophen and Caffeine*

*Pain Reliever / Pain Reliever Aid*

*Aspirin Free*

**24 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 0067-8139-01

# EXCEDRIN®

## TENSION HEADACHE

*Aspirin Free*

*Acetaminophen and Caffeine*  
*Pain Reliever/Pain Reliever Aid*

**24**  
**CAPLETS**



Principal Display Panel (Excedrin Extra Strength)

NDC 0067-2000-91

**EXCEDRIN®**

**EXTRA STRENGTH**

**Acetaminophen, Aspirin (NSAID) and Caffeine**

**Pain Reliever / Pain Reliever Aid**

**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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Visit us at [www.excedrin.com](http://www.excedrin.com)

**DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME. USE PRODUCTS AS DIRECTED.**

46172044



**EXCEDRIN EXTRA STRENGTH AND EXCEDRIN TENSION HEADACHE**

acetaminophen, aspirin (nsaid), and caffeine kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-8151
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0067-8151-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	09/30/2018
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### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	24
Part 2	1 BOTTLE	100

### Part 1 of 2

#### EXCEDRIN TENSION HEADACHE

acetaminophen, caffeine tablet, film coated

### Product Information

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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### 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		
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	12/15/2016	

**Part 2 of 2****EXCEDRIN EXTRA STRENGTH PAIN RELIEVER**

acetaminophen, aspirin (nsaid), and caffeine tablet, film coated

**Product Information**

Item Code (Source)	NDC:0067-2000
Route of Administration	ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

**Inactive Ingredients**

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	WHITE (White)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule-Shaped Tablet)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	E
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-2000-91	1 in 1 CARTON		
1		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	09/27/2006	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/30/2018	

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

Revised: 11/2018

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC