

**EXCEDRIN PM TRIPLE ACTION CAPLETS AND EXCEDRIN EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin (nsaid), caffeine, and diphenhydramine citrate**  
**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 PM Headache**

[Enter Generic Section here]

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

Acetaminophen 250 mg

Aspirin 250 mg (NSAID\*)

Diphenhydramine citrate 38 mg

\*nonsteroidal anti-inflammatory drug

***Purposes***

Pain reliever

Pain reliever

Nighttime sleep-aid

***Uses***

- for the temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

***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 2 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

#### **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.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age

#### **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
- you have glaucoma
- you have a breathing problem such as emphysema or chronic bronchitis
- you have trouble urinating due to an enlarged prostate gland

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

- a prescription drug for:
  - diabetes
  - gout
  - arthritis

- any other drug, or are under a doctor's care for any serious condition
- any product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer
- sedatives or tranquilizers

### **When using this product**

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

### **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
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- pain gets worse or last for more than 10 days
- painful area is red or swollen
- ringing in the ears or a loss of hearing occurs
- 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**
- do not use in children under 12 years of age
- adults and children 12 years of age and over: take 2 caplets at bedtime, with a full glass of water
- do not take more than 2 caplets in 24 hours, unless directed by 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, calcium carbonate, FD&C blue#1 aluminum lake, hydroxypropyl cellulose low substituted, hypromellose, magnesium stearate, maltodextrin, medium-chain triglycerides, polydextrose, polysorbate 80, povidone, pregelatinized corn starch, silicified microcrystalline cellulose, stearic acid, talc, titanium dioxide, yellow iron oxide, zinc stearate

### ***Questions or comments?***

**1-800-452-0051**

### **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?***

**1-800-452-0051**

**Principal Display Panel (Excedrin PM Headache)**

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

**NDC 0067-2056-24**

***EXCEDRIN®***

***PM HEADACHE***

***Acetaminophen, Aspirin (NSAID) and Diphenhydramine Citrate***

***Pain Reliever/Nighttime Sleep-Aid***

***Triple Action Formula***

***Caffeine-Free***

***Non-Habit Forming***

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

46172695

*Triple Action Formula*

NDC 0067-2058-24

# **EXCEDRIN<sup>®</sup>**

## **PM HEADACHE**

*Acetaminophen, Aspirin (NSAID)  
and Diphenhydramine Citrate*

*Pain Reliever / Nighttime Sleep-Aid*

*Caffeine-Free  
Non-Habit Forming*

**24  
CAPLETS**



**Principal Display Panel (Excedrin Extra Strength)**

**NDC 0067-2000-91**

**EXCEDRIN<sup>®</sup>**

**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



NDC 0067-2000-91

# EXCEDRIN®

## EXTRA STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine  
Pain Reliever/Pain Reliever Aid

100  
CAPLETS



### EXCEDRIN PM TRIPLE ACTION CAPLETS AND EXCEDRIN EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin (nsaid), caffeine, and diphenhydramine citrate kit

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-8148
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#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8148-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	05/01/2018	

#### Quantity of Parts

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

#### Part 1 of 2

#### EXCEDRIN PM TRIPLE ACTION CAPLETS

acetaminophen, aspirin (nsaid) and diphenhydramine citrate tablet, coated

**Product Information****Item Code (Source)** NDC:0067-2056**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
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

**Inactive Ingredients**

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ZINC STEARATE (UNII: H92E6QA4FV)	

**Product Characteristics**

<b>Color</b>	BLUE (light blue)	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	EXPM
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-2056-24	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	09/24/2014	

## 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: HBR47K3TBD)	
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

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

**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	05/01/2018	

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

Revised: 11/2018

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC