EXCEDRIN PM TRIPLE ACTION CAPLETS AND EXCEDRIN EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin (nsaid), caffeine, and diphenhydramine citrate
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

Excedrin PM Headache

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

Visit us at www.excedrin.com

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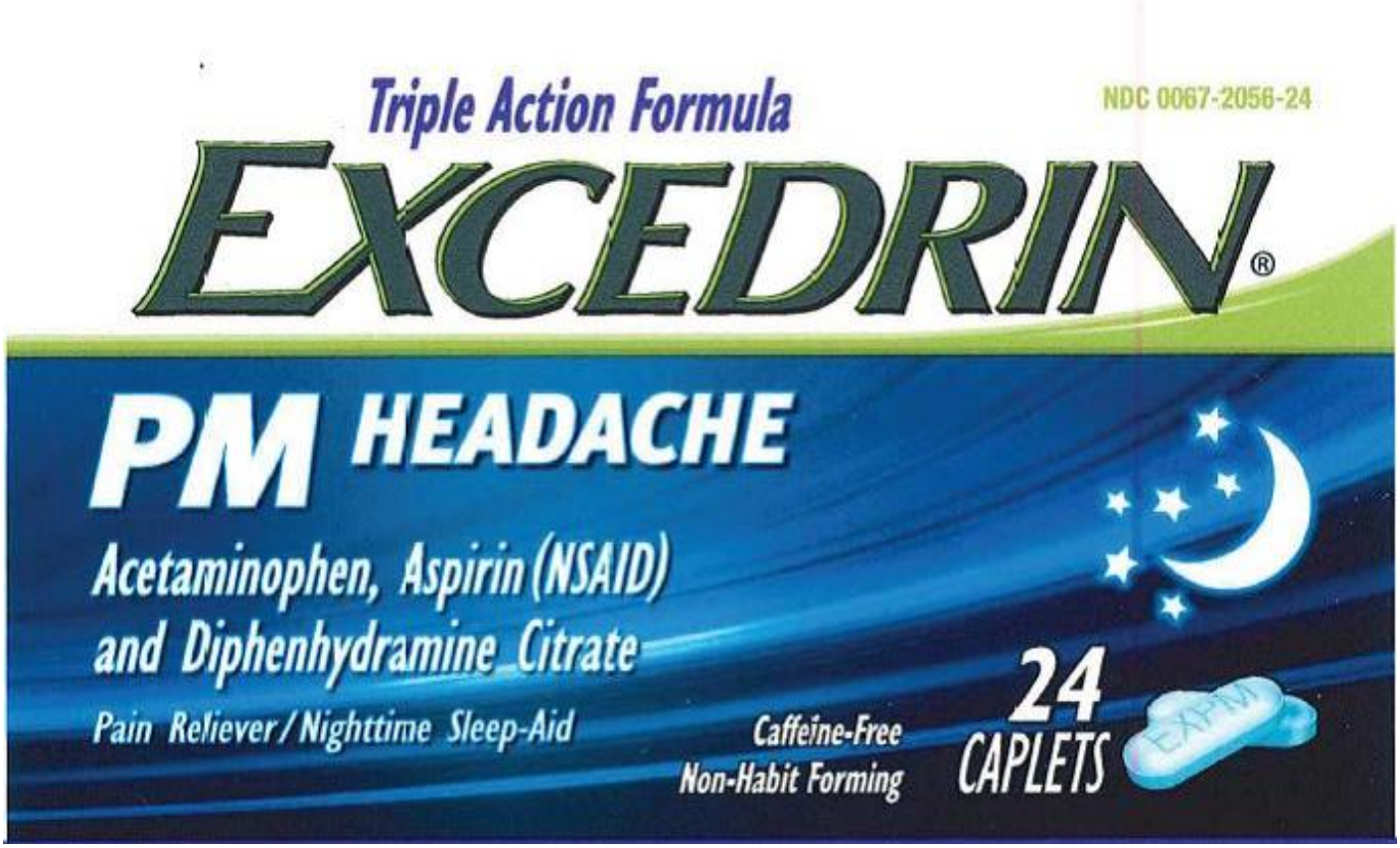

Principal Display Panel (Excedrin Extra Strength)

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

Visit us at www.excedrin.com

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

DIRECTED.

46172044

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

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

Color	BLUE (light blue)	**Score**	no score
Shape	RECTANGLE	**Size**	17mm
Flavor		**Imprint Code**	EXPM
Contains			

Packaging

			Marketing Start	Marketing End

#	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 Drug	M010	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: 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			
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 Drug	M013	09/27/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/01/2018	

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

Revised: 11/2023 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC