

**EXCEDRIN EXTRA STRENGTH HEADACHE- acetaminophen, aspirin (nsaid),  
caffeine tablet, film coated**  
**R J General Corporation**

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**EXCEDRIN  
EXTRA STRENGTH HEADACHE**

**Acetaminophen 250mg, Aspirin 250mg(NSAID) and Caffeine 65mg**

**Pain Reliever/Pain Reliever Aid**

<b>Active ingredients (in each tablet)</b>	<b>Purpose</b>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID) *	Pain reliever
Caffeine 65 mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - toothache
  - premenstrual and 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 loss of hearing occurs
- 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
- 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 at 20 weeks or later in 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 of age 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, carbuna wax, FD&C no.1, hypromellose, light mineral oil, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, polysorbate 20, povidine, propylene glycol, simethicone, sorbitan monolaurate, stearic acid, titanium dioxide

***Questions or comments?***

**1-800-468-7746**

**PRINCIPAL DISPLAY PANEL**

**Acetaminophen 250mg, Aspirin 250mg(NSAID) and Caffeine 65mg - NDC 70264-045-01 - Carton Label**



# EXCEDRIN EXTRA STRENGTH HEADACHE

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

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC: 70264-045(NDC:0067-2002)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 2165RE0K14)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITAN MONOLAURATE</b> (UNII: 6W9PS8B71J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<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:70264-045-01	25 in 1 CARTON	11/11/2024	
1		2 in 1 POUCH; 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	11/11/2024	

**Labeler** - R J General Corporation (122542830)

**Establishment**

Name	Address	ID/FEI	Business Operations
R J General Corporation		122542830	repack(70264-045)