

**EXCEDRIN EXTRA STRENGTH GELTABS- acetaminophen, aspirin,  
caffeine tablet, coated**  
**Haleon US Holdings LLC**

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***Drug Facts***

***Active ingredients (in each GelTab)***

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 gels 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 appear
- 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 3 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 gels every 6 hours; not more than 8 gels 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 yellow #10 aluminum lake, edetate disodium, FD&C blue #1, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, gelatin, glycerin, hypromellose, iron oxide black, isopropyl alcohol, lactose monohydrate, light mineral oil, low-substituted

hydroxypropyl cellulose, maltitol syrup, medium-chain triglycerides, microcrystalline cellulose, pepsin, polysorbate 20, povidone, propyl gallate, propylene glycol, simethicone, sorbitan monolaurate, stearic acid, titanium dioxide

***Questions?***

**1-800-452-0051**

**Principal Display Panel**

**NDC 0067-2021-20**

***EXCEDRIN***

***EXTRA STRENGTH***

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

***Pain Reliever/Pain Reliever Aid***

***20 GELTABS***

**TAMPER-EVIDENT BOTTLE**

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

Distributed by: **GSK Consumer Healthcare**

Warren, NJ 07059

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NDC 0067-2021-20

# EXCEDRIN®

## EXTRA STRENGTH

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

20  
GELTABS



### EXCEDRIN EXTRA STRENGTH GELTABS

acetaminophen, aspirin, caffeine tablet, coated

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-2021
<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>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)
<b>LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 2165RE0K14)
<b>MALTITOL</b> (UNII: D65DG142WK)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)
<b>PEPSIN</b> (UNII: GID333S43J)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SORBITAN MONOLAURATE</b> (UNII: 6W9PS8B71J)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	GREEN (dark green) , WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<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:0067-2021-20	1 in 1 CARTON	09/13/2011	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0067-2021-24	1 in 1 CARTON	09/13/2011	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0067-2021-80	1 in 1 CARTON	09/13/2011	
3		80 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	09/13/2011	

**Labeler** - Haleon US Holdings LLC (079944263)

