

**EXCEDRIN MIGRAINE GELTABS- acetaminophen, aspirin, caffeine tablet, coated**  
**GlaxoSmithKline Consumer Healthcare Holdings (US) 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

***Use***

- treats migraine

***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 geltabs 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

**Medication overuse headache warning:** Headaches may worsen if this product is used for 10 or more days per month.

**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 never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- 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 problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

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

- taking a prescription drug for:

- diabetes
- gout
- arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

### **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
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

### **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**
- adults: take 2 geltabs with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 geltabs in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

### ***Other information***

- store at controlled room temperature 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, disodium EDTA, FD&C blue #1, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, ferric oxide, gelatin, glycerin, hydroxypropylcellulose, hypromellose, isopropyl alcohol, lactose monohydrate, light mineral oil, maltitol solution, medium-chain triglycerides, microcrystalline cellulose, pepsin, polysorbate 20, povidone, propyl gallate, propylene glycol, simethicone emulsion, sorbitan monolaurate, stearic acid, titanium dioxide

**Questions?**

**1-800-452-0051**

**Principal Display Panel**

**0067-2035-20**

*See new warnings information*

*Excedrin®*

*Migraine*

*Acetaminophen, Aspirin (NSAID) and Caffeine*

*Pain reliever / Pain Reliever Aid*

**20 GELTABS\***

*\*GELATIN COATED TABLETS*

**TAMPER-EVIDENT BOTTLE**

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

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See new warnings information

NDC 0067-2035-20

# EXCEDRIN®

## MIGRAINE

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever / Pain Reliever Aid

20  
GELTABS\*

\*GELATIN COATED TABLETS



### EXCEDRIN MIGRAINE GELTABS

acetaminophen, aspirin, caffeine tablet, coated

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-2035
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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)
<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:0067-2035-20	1 in 1 CARTON	09/13/2011	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0067-2035-24	1 in 1 CARTON	09/13/2011	12/31/2014
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0067-2035-50	1 in 1 CARTON	09/13/2011	12/31/2014
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0067-2035-80	1 in 1 CARTON	09/13/2011	
4		80 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0067-2035-91	2 in 1 CARTON	09/13/2011	12/31/2014
5		100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0067-2035-16	2 in 1 CARTON	09/13/2011	12/31/2014
6		160 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020802	09/13/2011	

