

EXCEDRIN MIGRAINE GELTABS- acetaminophen, aspirin, caffeine tablet, coated

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

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 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

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 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**
- adults: take 2 gels with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 gels 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 no. 10 aluminum lake, edetate disodium, FD&C blue no. 1, FD&C blue no. 1 aluminum lake, FD&C red no. 40 aluminum lake, ferrous ferric oxide, gelatin, glycerin, hypromellose, isopropyl alcohol, lactose monohydrate, light mineral oil, low-substituted hydroxypropyl cellulose, maltitol solution, 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

Additional Information

TAMPER-EVIDENT BOTTLE

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

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Principal Display Panel

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Excedrin

Migraine

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever / Pain Reliever Aid

*20GELTABS**

**GELATIN COATED TABLETS*

NPA004482 Carton Front

NDC 0000-0000-00

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 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	

MALTITOL (UNII: D65DG142WK)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
PEPSIN (UNII: GID333S43J)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)
PROPYL GALLATE (UNII: 8D4SNN7V92)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
DIMETHICONE (UNII: 92RU3N3Y1O)
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	GREEN (dark green) , WHITE	Score	no score
Shape	ROUND	Size	18mm
Flavor		Imprint Code	E
Contains			

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
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NDA	NDA020802	09/13/2011	
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Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 7/2021

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC