

ACETAMINOPHEN, ASPIRIN AND CAFFEINE- acetaminophen, aspirin and caffeine tablet
Granules India Ltd

Acetaminophen, Aspirin and Caffeine Tablets USP, 250 mg, 250 mg and 65 mg

ACTIVE INGREDIENT(S)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID*)

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever

Pain reliever

Pain reliever aid

USE(S)

- 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 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

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

- taking a prescription drug for:
 - o diabetes
 - o gout
 - o 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 DOCTOR IF

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding :
 - o feel faint
 - o vomit blood
 - o have bloody or black stools
 - o 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 caplets with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

OTHER INFORMATION

- store at controlled room temperature 20° to 25°C (68° to 77°F)

- close cap tightly after use
- read all product information before using. Keep this box for important information.
- **Tamper Evident : Do not use if foil inner seal under the cap is opened or missing**

INACTIVE INGREDIENTS

Carnauba wax, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, propylene glycol, sodium stearyl fumarate and titanium dioxide

QUESTIONS OR COMMENTS?

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

Manufactured by:

Granules India Limited

Hyderabad-500 043, India

MADE IN INDIA

Distributed By:

Granules USA, Inc.

Parsippany, NJ 07054

PRINCIPAL DISPLAY PANEL

Labeling Format Information	
Format	Description
Font Style	Helvetica Narrow, Bold, Italic
Drug Facts	10 pt
Drug Facts (continued)	10 pt
Headings	8 pt
Sub-Headings	6 pt
Body Text	6 pt
Bullet	5 pt
Barline	2 pt
Headerline	0.5 pt
Version	00
Revision	00

NDC 62207-680-51

Compare to the active ingredient of Excedrin[®] Migraine

MIGRAINE RELIEF

Acetaminophen, Aspirin and Caffeine Tablets, USP

250 mg, 250 mg and 65 mg

Pain Reliever / Pain Reliever Aid

10 Caplets[†]
(Capsule-Shaped Tablets)



TAMPER-EVIDENT BOTTLE
DO NOT USE IF RUBBER FOIL SEAL IMPRINTED WITH "SEAL" IS BROKEN OR MISSING

Drug Facts

Active ingredients (in each caplet)	Purposes
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID)*	Pain reliever
Caffeine 65 mg	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 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

Drug Facts (continued)

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.

Drug Facts (continued)

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

Other information

- store at room temperature 20° to 25°C (68° to 77°F)
- close cap tightly after use
- read all product information before using.

Inactive ingredients: carnauba wax, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, sodium stearyl fumarate and titanium dioxide

Questions or comments?
Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

This product is not manufactured or distributed by GSK consumer healthcare, distributor of Excedrin[®] Migraine

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NDC 62207-680-51

Compare to the active ingredient of Excedrin[®] Migraine

MIGRAINE RELIEF

Acetaminophen, Aspirin and Caffeine Tablets, USP

250 mg, 250 mg and 65 mg

Pain Reliever / Pain Reliever Aid

10 Caplets[†]
(Capsule-Shaped Tablets)

Drug Facts

Active ingredients (in each caplet)	Purposes
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID)*	Pain reliever
Caffeine 65 mg	Pain reliever aid

*nonsteroidal anti-inflammatory drug

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.

Un Varnished Area for
Batch Coding details

Manufactured by:
GSK Consumer Healthcare
Parsippany, NJ 07054

Distributed by:
GSK Consumer Healthcare
Parsippany, NJ 07054

This product is not manufactured or distributed by GSK consumer healthcare, distributor of Excedrin[®] Migraine

Page no. 2

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NDC 62207-680-47

Compare to the active ingredient of Excedrin[®] Migraine

MIGRAINE RELIEF

Acetaminophen, Aspirin and Caffeine Tablets, USP

250 mg, 250 mg and 65 mg

Pain Reliever / Pain Reliever Aid

500 Caplets[†]
(*Capsule-Shaped Tablets)



Drug Facts

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

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
- blister
- 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

User 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 a stomach ulcer or bleeding problems

Unlabeled Area for
Batch Coding details

Manufactured by:
Granules India Limited
Hyderabad - 500 048, India
MADE IN INDIA

Distributed By:
Granules USA, Inc.
Parametry, NJ 07654

20000002000X
M.L. 3107170003FR



Drug Facts (continued)

- Take a blood thinning (anticoagulant) or steroid drug
- Use other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- Take 3 or more alcoholic drinks every day while using the product
- Use more or for longer than instructed
- Medication overdose headache warning: Headaches may worsen if this product is used for 10 or more days per month.
- Caffeine warning:** The recommended dose of the 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 a migraine 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 blurred and stiff neck
- you have had headaches beginning after or caused by head injury, exertion, coughing or sneezing
- you experience your first headache after the age of 50
- you have a regular headache
- you have a history of disease
- stomach bleeding warning applies to you
- you have liver disease
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, kidney disease, or other disease
- you are taking a diuretic
- you have asthma
- you have problems or serious side effects from taking pain relievers of their classes
- you have vomiting with your migraine headaches

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for:
 - obesity
 - 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. Get medical help right away.
- you experience any of the following signs of stomach bleeding:
 - heart burn
 - nausea
 - stomach or back pain
 - black or tarry stools
 - stools that are red or black
 - your migraines do not decrease or worsen after first dose
 - new or worse headache symptoms occur
 - ringing in the ears or loss of hearing occurs

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last months of pregnancy unless directly recommended 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
- shake bottle 2-3 times with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- under 18 years of age, ask a doctor

Other information

- store at room temperature 20° to 25°C (68° to 77°F)
- avoid exposure to heat
- do not use caplets after use
- resist all product promotion before using
- Tempo Evolve: Do not use if foil inner seal under the caplet is opened or missing

Inactive ingredients: Carboxymethylcellullose, hydroxypropyl methylcellullose, croscarmellose sodium, polyethylene glycol, sodium lauryl sulfate and titanium dioxide

Questions or comments?
Contact 1-877-762-3333, Mon-Fri 8:00 AM EST to 5:00 PM EST.

This product is manufactured and distributed by GSK consumer healthcare, distributor of Excedrin[®] Migraine

Acetaminophen, Aspirin and Caffeine Tablets USP 250mg, 250mg, 65mg

Each film coated tablet contains
Acetaminophen USP 250mg, Aspirin USP 250mg, Caffeine USP 65mg

Batch No.	: XXXXXXX	No. of Units	: 5 x 4500
Mfg. Dt.	: YYYY/MM	Gross Wt.	: 60.000 Kg
Exp. Dt.	: YYYY/MM	Tare Wt.	: 60.000 Kg
Mfg.Lic.No.	: 37/RR/AP/2003/F/R	Net Wet.	: 60.000 Kg
NDC No.	: 62207-680-98	Box No.	: 600

Storage : Store at 20-25°C (68-77°F)

Caution : For repacking only.



(01)50362207680986(17)YYMMDD(10)XXXXXX

Country of Origin: INDIA



(90)189038320000000004

FG Code:70000002515

Acetaminophen, Aspirin and Caffeine Tablets USP 250mg, 250mg, 65mg

Each film coated tablet contains
Acetaminophen USP 250mg, Aspirin USP 250mg, Caffeine USP 65mg

Batch No. : XXXXXXXX No. of Units : 4500
Mfg. Dt. : YYYY/MM
Exp. Dt. : YYYY/MM
Mfg.Lic.No. : 37/RR/AP/2003/F/R
NDC No. : 62207-680-99
Storage : Store at 20-25°C (68-77°F)
Caution : For repacking only.

Country of Origin: INDIA

FG Code:700000002515

ACETAMINOPHEN, ASPIRIN AND CAFFEINE

acetaminophen, aspirin and caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-680
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
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Capsule shaped Tablet)	Size	17mm
Flavor		Imprint Code	I1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-680-51	1 in 1 CARTON	04/15/2021	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62207-680-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	
3	NDC:62207-680-98	22500 in 1 BOX; Type 0: Not a Combination Product	04/15/2021	
4	NDC:62207-680-99	4500 in 1 POUCH; Type 0: Not a Combination Product	04/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214039	04/15/2021	

Labeler - Granules India Ltd (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Ltd		918609236	analysis(62207-680) , label(62207-680) , manufacture(62207-680) , pack(62207-680)

Revised: 12/2025

Granules India Ltd