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

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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	
Fant Style	Helvelica Narrow, Bold, Italic	
Drug Facts	10pt	
Drug Facts (continued)	10 pt	
Headings	8pt	
Sub Headings	6pt	
Body Text	6pt	
Bullet	5pt	
Barline	2 pt	
Heirine	0.5 pt	
Version	02	
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 INNER FOIL'S EAL IMPRINTED WITH "SEALED for YOUR PROTECTION" IS BROKEN OR

### Drug Facts

### Active ingredients (in each caplet)

Purposes

Acetaminophen 250 mg
Aspirin 250 mg (NSAID\*)
Caffeine 65 mg
\*nonsteroidal anti-inflammatory drug

Use • treats migraine

Warnings
Reye's syndrome: Children and teeragers who have or are recovering from chicken pox or fu-like symptoms should not use this product. When using this product, changes in behavior with nausea and vomiting cour, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious liness.
Allergy alert:
Acetaminophen may cause severe skin reactions.
Symptoms may include:
- skin redefanting - blisters - rash
It a skin reaction occurs, stop use and seek medical help right away.

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which may include:

hives • facial swelling • asthma (wheezing) • shock

hines - facial swelling - asthma (wheezing) - shock
Liver warming:
This product contains acetaminophen. Severe liver damage
may occur if you take
- more than 2 captes 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 warming:
product contains an NSAID, which may cause severe
stomach bleeding. The chance is higher if you
- are age 60 or older
- have had stomach uloss or bleeding problems
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- take other drugs containing prescription or nonprescription
NSAIDs (applin, buprofen, reproxen, or others)
- have 3 or more alcoholic drinks every day while using this
product

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, leeplessness, and, occasionally, rapid heart beat.

if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever.

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

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you have the worst headache of your life
you have two rand stiff nock
you have headaches beginning after or caused by head
injury, enertion, coughing or bending
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you have day reactions; you have migraine so severe as to require bed rest you have her 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 of second.

or kidney disease you are taking a diuretic

Purposes

Pain reliever

you have asthma you have problems or serious side effects from taking pain relevers or flower reducers you have vomiting with your migraine headache

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

 taking any other drug
 taking any other product that contains aspirin. acetaminophen, or any other pain relie

### Drug Facts (continued)

Stop use and ask a doctor if

an allegic reaction occurs. Seek medical help right away.
you experience any of the following signs of stomach bleeding:

-teel 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

It pregnant or breast-feeding, ask a health professional before use. It is especially important not bus use aspirar during he 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 Poisson Control Center inght away. Outlok medical attention is critical for adults as well as for children even if you do not only not provided to the control of the order of the order

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 pensist 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: carrauba wax, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, sodium stearyl fumarate and titanium

# 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

# Page no. 1

### NDC 62207-680-51

Compare to the active ingredient of Excedrin Migraine

Acetaminophen, Aspirin and Caffeine Tablets, USP

250 mg, 250 mg and 65 mg

(Capsule-Shaped Tablets)

Pain Reliever / Pain Reliever Aid 10 Caplets'

### **Drug Facts**

Active ingredients

(in each caplet)

Aspirin 250 mg (NSAID\*) Caffeine 65 mg \*nonsteroidal anti-inflammatory drug

Use . treats migraine

### Warnings

Reye's syndrome: Children and teenages 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 nauses and vomiting coour, consult a doctor because these symptoms could be an early sign of Raye's syndrome, a rare but serious liness.

Un Vamished Area for Bath Coding details

Manufactured by: Granut as India Limited Hydrochid — SQC 040, India MAQCIN NDIA Datibutedby Grand in USA, Inc. Perappers, N 07054

This product is not manufadured or distributed by GSK consumer healthcare, distributer of Excelent\* Migraine





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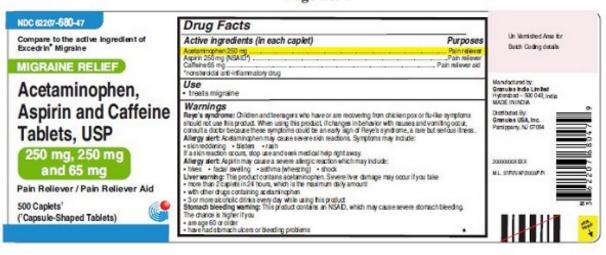
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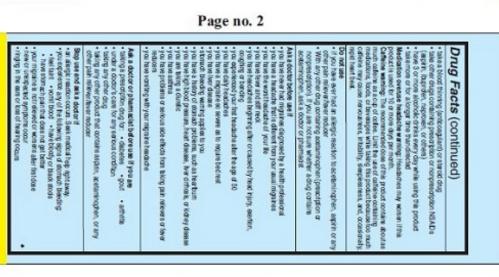
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### Page no. 3

This products actiman believed or delibrary of Experient Magrane administration of Experient Magrane	Questions or comments? Cortact 1477-770-335 Nov-Fit 8:00 AM EST to 5:00 P M P ST.	hadive ingredents: Carnauta was, hydrospropy celulose, hypronelose, morcopysialine celulose, polyetnylere glycol, sodum steary fumorate and stantum doutde	Other information  Other information  -ctice capingthy after use  -ctice capingthy after use  -ctice product information before using.  Tamper Endends Too ond use if foil inner seal under the cap is opened or missing.	Directions  Oned use more than directed of wider  - adults load a capte with a glass of wider  - symptom per six or wires, pay your doctor  - direction error than 2 capteins of Anom, unless directed by a coctor  - under 18 years of age ask a chopy	Keep Out of Reach of Children In case of excitose, getimed all helper contact. a Prosen Cyenne of a way. Quot medosi attention is official for adults as well as for children even if you do not notice any aligns or symptoms.	If pregnant or breashfeeding, ask a health prolessional before use. It is especially imported not to use expirit during the last Smooths of pregnatory unless addrained declaration to extra breasane it may esture problems in the unborn of high or complications during delivery.	Drug Facts (continued)
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# 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)XXXXXXX

Country of Origin: INDIA

FG Code:700000002515

# 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	<b>Basis of Strength</b>	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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	11	
Contains				

P	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: 9/2023 Granules India Ltd