

**CAFIZETAMOL FORTE- acetaminophen, caffeine tablet, film coated
OPMX LLC**

CAFIZETAMOL FORTE

Active ingredients (in each caplet)

Acetaminophen 500 mg

Caffeine 65 mg

Purposes

Pain reliever

Pain reliever aid

Uses

- temporarily relieves minor aches and pain due to:
- headache
- muscular aches

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 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

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 heartbeat.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.

Ask a doctor before use if

you have liver disease

Ask a doctor or pharmacist

if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- any new symptoms occur
- symptoms do not get better or worsen
- 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

If pregnant or breast-feeding,

ask a health professional before use.

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 exceed recommended dosage
- adults and children 12 years and over: take 2 caplets every 6 hours; do not take more than 6 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at controlled room temperature 20°-25°C (68°-77°F)
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #27, FD&C blue #1, FD&C yellow #6, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, polyvinylpyrrolidone, stearic acid, talc, titanium dioxide.

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM EST or www.healthlifeofusa.com

Principal Display Panel

NDC 69729-147-40

CAFIZETAMOL FORTE

Superior Pain, Cold & Fever Relief

NDC 69729-147-40

CAFIZETAMOL FORTE

Acetaminophen 500 mg / Pain reliever
Caffeine 65 mg / Pain reliever aid

Superior Pain, Cold & Fever Relief

- HEADACHE
- MUSCLE PAIN
- BACKACHE
- CRAMPS
- TOOTHACHE

40 Caplets

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen 500 mg..... Pain reliever

Caffeine 65 mg..... Pain reliever aid

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 grams every day, which is the maximum daily amount
- with other drugs containing acetaminophen
- 8 or more alcoholic drinks every day while using this product

■ 3 or more alcoholic drinks every day while using this product

■ caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use ■ with any other drug containing acetaminophen (prescription or over-the-counter) unless your doctor tells you to.

Ask a doctor before use if you have liver disease.

Directions

Take 2 tablets every 6 hours.

■ adults and children 12 years and over: Take 2 tablets every 6 hours.

■ children under 12 years: Ask a doctor.

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Exclusively distributed by:

FRX

San Diego, CA

Phone: 619-690-5633

Lot No. NO VARNISH AREA

Exp. Date: 8 10053 18122 5

NDC 69729-147-40

CAFIZETAMOL FORTE

Acetaminophen 500 mg / Pain reliever
Caffeine 65 mg / Pain reliever aid

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Ask a doctor before use if you have liver disease.

Ask a doctor or pharmacist if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- any new symptoms appear
- symptoms do not get better or worsen
- pain 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

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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions

- do not exceed recommended dosage.
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- children under 12 years: ask a doctor.

Other information

- store at controlled room temperature 20°-25°C (68°-77°F).
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, D&C red #27, FD&C blue #1, FD&C yellow #6, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, polyvinylpyrrolidone, stearic acid, tan, titanium dioxide

Questions or comments? Call toll free 1-844-822-1188 Monday through Friday 9AM - 5PM EST or www.thebraintrust.com

MADE IN USA

Exclusively distributed by:

FRX

San Diego, CA

Phone: 619-690-5633

Lot No. NO VARNISH AREA

Exp. Date: 8 10053 18122 5

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-147
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL ((Caplet))	Size	17mm
Flavor		Imprint Code	5431
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-147-40	1 in 1 CARTON	08/09/2023	
1		40 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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OTC Monograph Drug	M013	08/09/2023	
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Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	label(69729-147) , manufacture(69729-147) , pack(69729-147)

Revised: 12/2024

OPMX LLC