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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

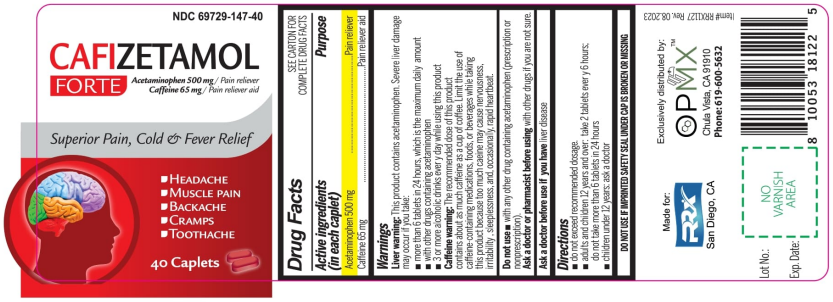
Principal Display Panel

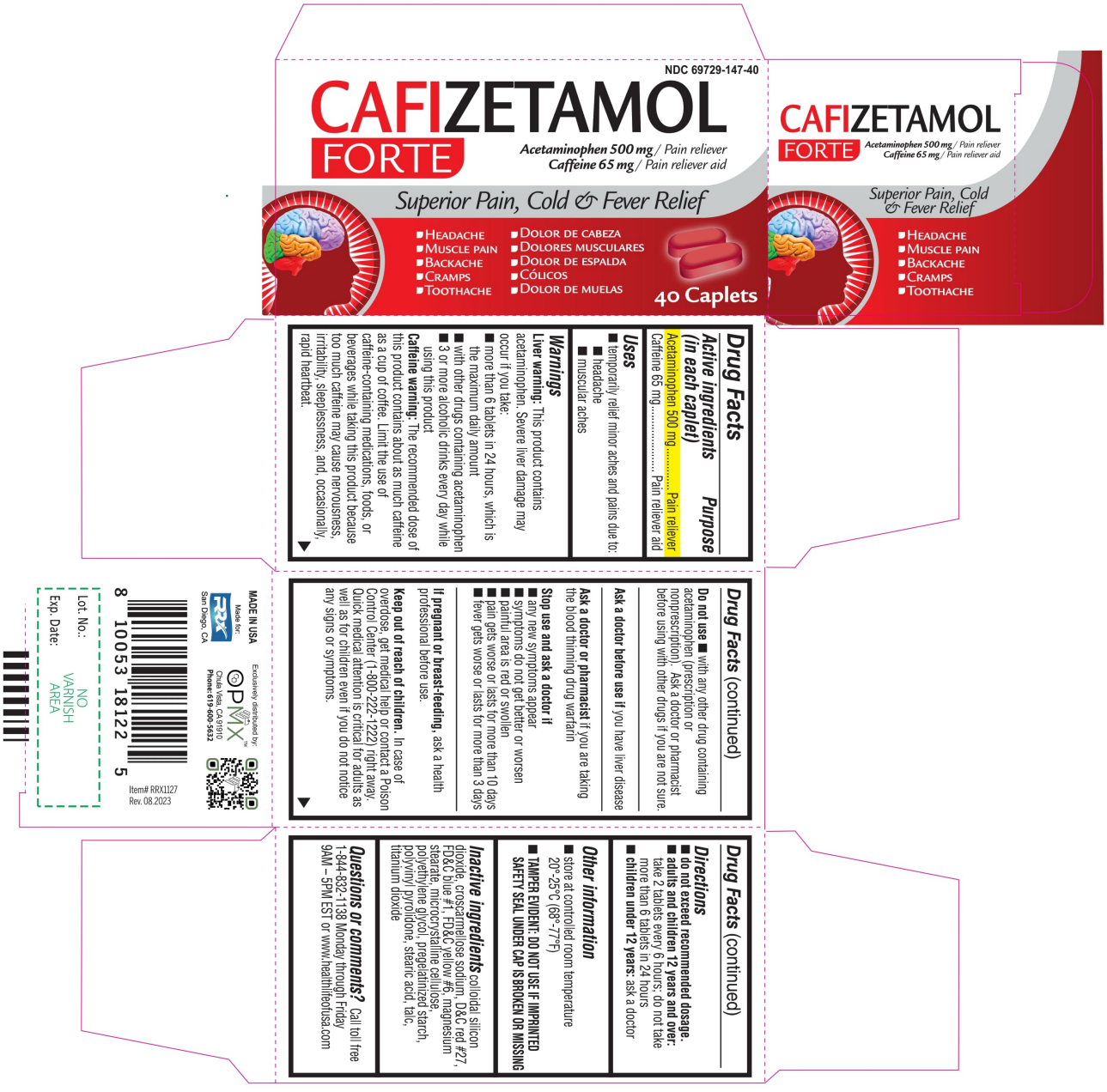
NDC 69729-147-40

CAFIZETAMOL FORTE

Superior Pain, Cold & Fever Relief

40 Caplets





CAFIZETAMOL FORTE

acetaminophen, caffeine tablet, film coated

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: 3WQ0SDW1A)	
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
OTC monograph not final	part343	08/09/2023	

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: 8/2023 OPMX LLC