DOLONEURO-TROPAS- acetaminophen, caffeine tablet, film coated OPMX LLC

DoloNeuro Tropas

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 (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.

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 PLEASE REFER TO LEAFLET FOR INSTRUCTIONS IN SPANISH.

CONSULTE EL FOLLETO PARA LAS INSTRUCCIONES EN ESPAÑOL.

Principal Display Panel

NDC 69729-795-24 DOLONEURO-TROPAS

NUEVA FÓRMULA

NEW FORMULA

Treat Pain of Inflammation caused by conditions such as:

Alivio temporal de dolores leves y malestares debidos a:

Reumatismo, Artritis, Inflamación, Dolor

Rheumatism, Arthritis, Inflammation, Pain

Box with 24 Caplets

Analgésico/Pain Reliever

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

Phone:619-600-5632











■ suy new symptoms appear Stop use and ask a doctor if

Ask a doctor before use if you have liver disease
Ask a doctor or pharmacist if you are taking the blood thinning drug drugs if you are not sure.

Do not use with anyother drug containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other above the property of the propert occasionally, rapid heartbeat.

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- with other drugs containing acetaminophen ■ more than 6 tablets in 24 hours, which is the máximum daily amount
- Liver warning: This product contains acetaminophen. Severe liver
 - wnscnlar aches Uses

 • temporarily relief minor aches and pains due to:

 - hondache

Caffeine 65 mg.

Pain reliever aid. Purpose Active ingredient (in each tablet)

Drug Facts

Questions of comments?
Call for the 619-600-5632 Monday through Friday 9AM - 5PM EST
PLEASE BEFER TO LLETO PARA LAS INSTRUCCIONES EN ESPAÑOL.
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■ fever gets worse or lasts for more than 3 days

> ■ symptoms do not get better or worsen Drug Facts (Continued)

DOLONEURO-TROPAS

Box with 24 Caplets

Box with 24 Caplets

Analgésico / Pain Reliever

DOLONEURO-TROPAS



Treat Pain or Inflammation caused by

y malestares debidos a:

Alivio temporal de dolores leves

- Reumatismo Artritis
- <u>Infl</u>amación



<u>Inflammation</u>







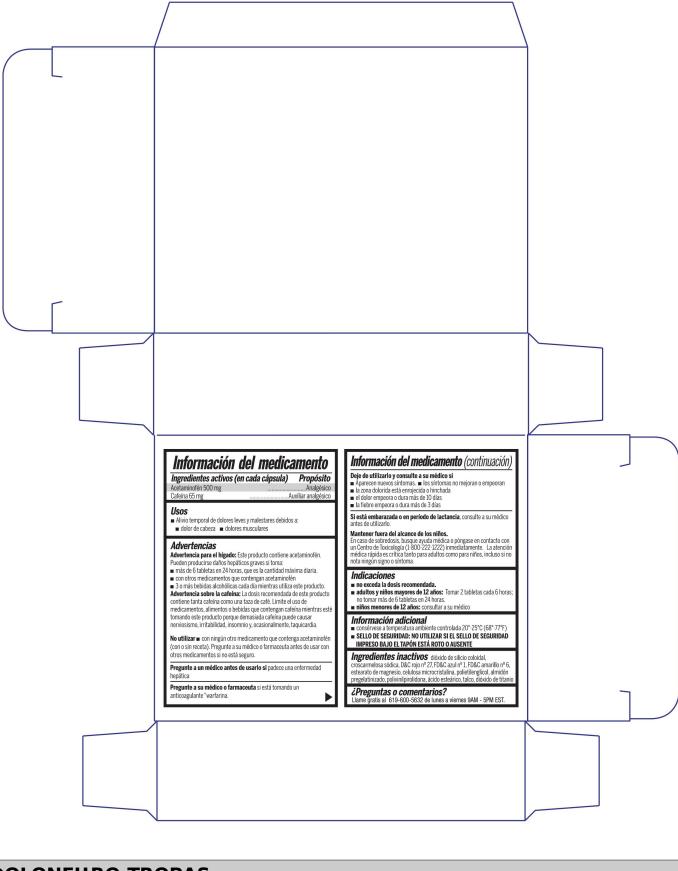
Analgésico / Pain Reliever

NO VANISH AREA

Lot. No.:

NO VANISH AREA

conditions such as:



DOLONEURO-TROPAS

acetaminophen, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-795
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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: M280L1HH48)			
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			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:69729- 795-24	2 in 1 CARTON	04/01/2025	
:	L	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/01/2025	

Labeler - OPMX LLC (029918743)

Establishment				
Name	Address	ID/FEI	Business Operations	
ELYSIUM PHARMACEUTICALS LIMITED		915664486	label(69729-795) , manufacture(69729-795) , pack(69729-795)	

Revised: 4/2025 OPMX LLC