KORTRIBION PAIN RELIEVER- acetaminophen, caffeine tablet, film coated OPMX LLC

KORTRIBION Pain Reliever

Active ingredients (in each tablet)

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 tablets every 6 hours; do not take more than 6 tablets 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 Medimex Inc. 302-318-1359 Monday through Friday 9AM-5PM EST

Principal Display Panel

NDC 69729-793-24

KORTRIBION

Treat Pain or Inflammation caused by conditions such as:

Alivio temporal de dolores leves y malestares debidos a:

Joint Pain

Articulaciones

Headache

Dolor de cabeza

Muscle Aches

Dolores musculares

Back Ache

Dolores de espalda

Inflamation

Inflamación

Arthritis

Artitris

Box with 24 caplets

Analgésico/Pain Reliever

Exclusively distributed by:

OPMX Chula Vista, CA 91910

Phone: 619-600-5632

Analgésico / Pain Reliever

Box with 24 Caplets

Alivio temporal de dolores leves y malestares debidos a:

conditions such as: Treat, Pain or Inflammation caused by

NDC 69729-74

Analgésico / Pain Reliever

Box with 24 Caplets

Drug Facts

Active ingredient (in each tablet)

Purpose

Uses temporarily relief minor aches and pains due to:

muscular aches

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: more than 6 tablets In 24 hours, which is the maximum daily amount

 with other drugs containing acetaminophen
 with other drugs containing acetaminophen
 a 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, imitability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use with anyother 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 appear

Drug Facts (Continued)

- 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
confact a Poison Control Center (1-800-222-1222) right away. Quick
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Questions or comments?

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Exclusively distributed by:



Chula Vista, CA 91910 Phone: 619-600-5632





Date

Lot.

Analgesico

Item # INX057 Rev. 02.2025

KORTRIBION PAIN RELIEVER

acetaminophen, caffeine tablet, film coated

Product	Inform	ation

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)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
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)		
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			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729- 793-24	2 in 1 CARTON	02/14/2025	
1		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	02/14/2025	

Labeler - OPMX LLC (029918743)

Establishment			
Na me	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	label(69729-793) , manufacture(69729-793) , pack(69729-793)

Revised: 2/2025 OPMX LLC