

**MIGRAFEIN 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.*

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**Migrafein 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](http://www.healthlifeofusa.com)

### **Principal Display Panel**

**NDC 69729-148-40**

Migrafein FORTE

40 Caplets

NDC 69729-148-40

# Migrafein FORTE

Acetaminophen 500 mg  
Pain reliever  
Caffeine 65 mg  
Pain reliever aid

40 Caplets



### SECTION FOR COMPLETE DRUG FACTS

### Drug Facts

**Active ingredients (in each caplet)**  
Acetaminophen 500 mg  
Caffeine 65 mg

**Purpose**  
Pain reliever  
Pain reliever aid

### Warnings

**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. Do not take more than 6 tablets in 24 hours. Do not take more than 6 tablets in 24 hours. Do not take more than 6 tablets in 24 hours. Do not take more than 6 tablets in 24 hours.

**Caffeine warning:** The recommended dose of this product contains caffeine. Caffeine is a stimulant. Excessive use of caffeine can cause nervousness, insomnia, and occasionally rapid heartbeat. Do not use with any other drug containing acetaminophen (prescription or over-the-counter) or alcohol. Do not use if you are taking any other drug containing acetaminophen (prescription or over-the-counter) or alcohol. Do not use if you are taking any other drug containing acetaminophen (prescription or over-the-counter) or alcohol.

**Do not use with any other drug containing acetaminophen (prescription or over-the-counter) or alcohol. Do not use if you are taking any other drug containing acetaminophen (prescription or over-the-counter) or alcohol.**

**Ask a doctor before use if you have liver disease, kidney disease, or are pregnant or breastfeeding.**

**Directions**  
Take 2 tablets every 6 hours, do not take more than 6 tablets in 24 hours. Children under 12 years: ask a doctor.

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

Manufactured for: **inovox** PARACETAMOL  
Chula Vista, CA 91910  
Phone: 619-600-5632

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Lot No.:  
Exp. Date:

NDC 69729-148-40

# Migrafein FORTE

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



# Migrafein FORTE

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

40 Caplets

- Headache
- Muscle pain
- Backache
- Cramps
- Toothache
- Dolor de cabeza
- Dolores musculares
- Dolor de espalda
- Cólicos
- Dolor de muelas

40 Caplets

- Headache
- Muscle pain
- Backache
- Cold Fever
- Cramps
- Toothache

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredients (in each caplet)</b> Acetaminophen 500 mg ..... Pain reliever Caffeine 65 mg ..... Pain reliever aid	
<b>Uses</b> Temporarily relieve minor aches and pains due to: ● headache ● muscular aches	
<b>Warnings</b> <b>Liver warning:</b> 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 ● 3 or more alcoholic drinks every day while using this product <b>Caffeine warning:</b> 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.	

<b>Drug Facts (continued)</b>	
<b>Do not use</b> with any other drug containing acetaminophen (prescription or over-the-counter). Ask a doctor or pharmacist before using with other drugs if you are not sure.	
<b>Ask a doctor before use</b> if you have liver disease or kidney disease.	
<b>Ask a doctor or pharmacist</b> if you are taking the blood thinning drug warfarin.	
<b>Stop use and ask a doctor if</b> ● any new symptoms appear ● symptoms do not get better or worsen ● painful areas are red or swollen ● pain gets worse or lasts for more than 10 days ● fever gets worse or lasts for more than 3 days	
<b>Keep out of reach of children.</b> 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.	

<b>Drug Facts (continued)</b>	
<b>Directions</b> 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	
<b>Other information</b> ● store at controlled room temperature 20°-25°C (68°-77°F) ● <b>TAPEE EVIDENT. DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING</b>	
<b>Inactive ingredients</b> colloidal silicon dioxide, croscarmellose sodium, D&C red #27, FD&C blue #1, FD&C yellow #6, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone, pregelatinized starch, titanium dioxide	
<b>Questions or comments?</b> Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM EST or <a href="http://www.healthinova.com">www.healthinova.com</a>	

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Lot No.:  
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NO VARNISH AREA

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Hum# INX020 Rev. 08.2023

# MIGRAFEIN FORTE

acetaminophen, caffeine tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-148
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-148-40	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(69729-148) , manufacture(69729-148) , pack(69729-148)

Revised: 8/2023

OPMX LLC