

SEDAL3X- acetaminophen, aspirin, caffeine tablet
OPMX LLC

Sedal 3X

Drug facts

Active ingredients
(in each caplets)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Uses

Uses
temporarily relieves minor aches and pains due to:
headache
a cold
arthritis
muscular aches
sinusitis
toothache
premenstrual and menstrual cramps

Warnings

Allergy alert

Aspirin may cause a severe allergic reaction, which may include:
hives
shock
facial swelling
asthma (wheezing)

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:
more than 8 tablets in 24 hours, wich is the maximum daily amount
with other drugs containing acetaminophen
3 or more alcoholic drinks every day while using this product

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance
is higher if you:
are age 60 or older

have had stomach ulcers or bleeding problems
take a blood thinning (anticoagulant) or steroid drug
take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
have 3 or more alcoholic drinks every day while using this product
take more or for a longer time than directed

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

if you ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

liver disease
stomach bleeding warning applies to you
you have a history of stomach problems, such as heartburn
you have high blood pressure, heart disease, liver cirrhosis or kidney disease
you have asthma
you are taking a diuretic

Ask a doctor or pharmacist before use if you are taking

a prescription drug for diabetes, gout, or arthritis
taking any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if

you experience any of the following signs of stomach bleeding:
feel faint
have bloody or black stools
vomit blood
have stomach pain that does not get better
an allergic reaction occurs. Seek medical help right away if:
any new symptoms appear
ringing in the ears or loss of hearing occurs
pain gets worse or lasts for more than 10 days
fever gets worse or lasts for more than 3 days
painful area is red or swollen

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during

the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery

Keep out of reach of children.

Overdose warning

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 use more than directed
drink a full glass of water with each dose
adults and children 12 years and over:
take 2 tablets every 6 hours
do not take more than 8 tablets in 24 hours
children under 12 years: ask a doctor

Other information

store at 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAPS IS BROKEN OR MISSING

Inactive ingredients

corn starch, crospovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Manufactured in:
GMP Registered Facility in the USA

Made for:

inov FARMACEUTIQUE

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

PHONE: 619-600-5632

Sedal3x

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

Pain Reliever

40 Caplets

PRINCIPAL DISPLAY PANEL - 40 CAPLETS

NDC 69729-055-40

Sedal3x

Acetaminophen 250 mg Pain reliever

Aspirin 250 mg Pain reliever

Caffeine 65 mg Pain reliever

40 Caplets

SEDAL3X

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-055
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
CROSPVIDONE (UNII: 2S7830E561)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-055-40	1 in 1 CARTON	09/07/2022	
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	09/07/2022	
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Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	analysis(69729-055) , label(69729-055) , manufacture(69729-055) , pack(69729-055)

Revised: 6/2024

OPMX LLC