

**SEDAL3X- acetaminophen, aspirin, caffeine tablet**  
**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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**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, which 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 69729-105-40

Seda3x

Acetaminophen 250 mg Pain reliever

Aspirin 250 mg Pain reliever


Caffeine 65 mg Pain reliever

40 Caplets

NDC 69729-055-40

# S=da13x

Acetaminophen 250 mg Pain reliever  
Aspirin 250 mg Pain reliever  
Caffeine 65 mg Pain reliever aid



**40 Caplets**

SEE CAUTION FOR COMPLETE DRUG FACTS

**Drug Facts**

**Active ingredient (in each tablet)**

Acetaminophen 250 mg Pain reliever  
Aspirin 250 mg Pain reliever  
Caffeine 65 mg Pain reliever aid

**Warnings**

Do not take more than 8 tablets in 24 hours, which is the maximum daily amount. Do not take more than 8 tablets in 24 hours, which is the maximum daily amount. Do not take more than 8 tablets in 24 hours, which is the maximum daily amount.

**Directions**

Take 1 or 2 tablets every 4 to 6 hours as needed for pain or fever. Do not take more than 8 tablets in 24 hours. Do not take more than 8 tablets in 24 hours. Do not take more than 8 tablets in 24 hours.

**Other information**

Keep this and all other medicines out of the reach of children. Do not use if the seal is broken or missing. Do not use if the seal is broken or missing. Do not use if the seal is broken or missing.

**Exclusively distributed by:**  
inovx Pharmaceuticals, Inc. USA  
PAIN RELIEVER  
NO WARNISH AREA  
Lot No.:  
Exp. Date:

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**Drug Facts (continued)**

**Do not use**

- if you are allergic to aspirin, salicylates, or other drugs containing aspirin or salicylates
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Manufactured by: **inovx** Pharmaceuticals, Inc. USA  
PAIN RELIEVER  
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Lot No.:  
Exp. Date:

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# SEDAL3X

acetaminophen, aspirin, caffeine tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-055
<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	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	S53
<b>Contains</b>			

## 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 not final	part343	09/07/2022	
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**Labeler - OPMX LLC (029918743)**

**Establishment**

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

Revised: 9/2022

OPMX LLC