

VAZALORE- aspirin capsule
PLx Pharma Inc

VAZALORE (aspirin) Capsules

Uses

- For temporary relief of minor aches and pains associated with:
- headache
- Backache
- muscular aches
- a cold
- toothache
- minor pains of arthritis
- premenstrual and menstrual cramps
- temporarily reduces fever
- n ask your doctor about other uses of aspirin capsules

Warnings

Warnings

Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

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

This product contains soy

Stomach bleeding warning: This product contains an NSAID, which may cause 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

Active Ingredient (in Each capsules)

Aspirin (NSAID)* 325mg

*Non steroidal Anti inflammatory Drug

Ask a doctor before use if:

- 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 are taking a diuretic
- You have asthma

Do not use If you have ever had an allergic reaction to aspirin or any other pain reliever / fever reducer

Ask a doctor or a pharmacist before you use if you are

- Taking a drug for diabetes, gout or arthritis

Stop use and ask a doctor

Stop use and ask a doctor if

- An allergic reaction occurs. Seek medical help right away
- You experience any of the following signs of stomach bleeding

- Feel faint - vomit blood - have bloody or black stool - have stomach pain that does not get better

- Pain gets worse or lasts more than 10 days
- Fever gets worse or lasts more than 3 days
- Ringing in the ears or loss of hearing occurs
- Redness and swelling is present in the painful area
- Any new symptoms occur. These could be signs of serious conditions

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

If pregnant or breast feeding, ask a healthcare 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

Purposes:

Aspirin (NSAID)* 325mg __ Pain reliever / fever reducer

*Non steroidal Anti inflammatory Drug

Questions or Comments

Questions or comments?

Call 1-888-842-3569 9:00 AM – 7:00 PM ET, Monday – Friday

RETAIN CARTON FOR COMPLETE WARNINGS AND INFORMATION

Other Information

Other Information

- Save carton for full directions and warnings
- Store at 15-30°C (59-86°F)

- Avoid excessive heat above 40°C (104°F)
- Do not use if the blue band around the capsule is missing or broken

Inactive ingredients

Anhydrous citric acid, carrageenan, colloidal silicon dioxide, FD&C blue #1, Hypromellose, lecithin, oleic acid, pharmaceutical ink, potassium chloride, soybean oil, titanium dioxide

Directions

Directions

- Drink a full glass of water with each dose
- Adults and children 12 years and over:
 - Take 1 or 2 capsules every 4 hours or 3 capsules every 6 hours while symptoms persist
 - Do not exceed 12 capsules in 24 hours
- Children under 12 years consult a doctor

30 Count Blister Carton

1 Bottle Inside

VAZALORE
Aspirin Capsules, 81 mg Pain Reliever/Fever Reducer (NSAID)

30 Liquid-Filled Capsules **81 mg LOW DOSE**

BOTTLE SHOWN ACTUAL SIZE

<p>Drug Facts</p> <p>Active ingredient (in each capsule) Purposes Aspirin (NSAID)* 81 mg.....Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p>Uses ■ for the temporary relief of minor aches and pains associated with: ■ headache ■ backache ■ muscular aches ■ a cold ■ toothache ■ minor pain of arthritis ■ premenstrual and menstrual cramps ■ temporarily reduces fever ■ ask your doctor about other uses for aspirin capsules</p> <p>Warnings Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness. Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ shock ■ asthma (wheezing) This product contains soy. 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</p>	<p>Drug Facts (continued)</p> <p>Do not use if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer.</p> <p>Ask a doctor before use if ■ 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 are taking a diuretic ■ you have asthma</p> <p>Ask a doctor or pharmacist before use if you are ■ taking a prescription drug for diabetes, gout or arthritis</p> <p>Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts for more than 3 days ■ ringing in the ears or loss of hearing occurs ■ redness or swelling is present in the painful area ■ any new symptoms occur. These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health care 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. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
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Consult your healthcare provider before using this product for your heart.

ASPIRIN THERAPY ™
VAZALORE
Aspirin Capsules, 81 mg Pain Reliever/Fever Reducer (NSAID)



30 Liquid-Filled Capsules

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL WITH REPEATED TEXT "SEALED FOR YOUR PROTECTION" UNDER CAP IS MISSING OR BROKEN.

Drug Facts (continued)

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over:
 - take 4 to 8 capsules every 4 hours while symptoms persist
 - do not exceed 48 capsules in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Other information

- save carton for full directions and warnings
- store at 15-30°C (59-86°F)
- avoid excessive heat above 40°C (104°F)
- do not use if the blue band around the capsule is missing or broken

Inactive ingredients anhydrous citric acid, carrageenan, colloidal silicon dioxide, FD&C Blue #1, hypromellose, lecithin, oleic acid, pharmaceutical ink, potassium chloride, soybean oil, titanium dioxide

Questions or comments?

Call 1-888-842-3567 9:00 AM - 7:00 PM ET, Monday - Friday



Distributed by: **PLx Pharma Inc.**
9 Fishers Lane, Sparta, NJ 07871
Visit us at: www.vazalore.com
Patents: www.vazalore.com/patents

RETAIN CARTON FOR COMPLETE WARNINGS AND INFORMATION

NDC 73089-081-21

Consult your healthcare provider before using this product for your heart.

New!

ASPIRIN THERAPY ™
VAZALORE
Aspirin Capsules, 81 mg Pain Reliever/Fever Reducer (NSAID)

81 mg
LOW DOSE

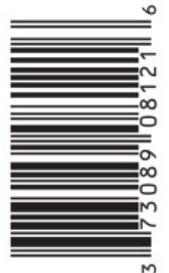
FIRST LIQUID-FILLED ASPIRIN CAPSULES™

30 Liquid-Filled Capsules



1-12345

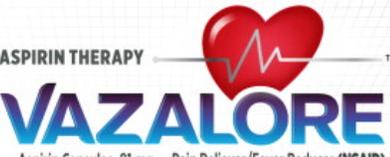
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NDC 73089-081-21 Consult your healthcare provider before using this product for your heart.

ASPIRIN THERAPY



VAZALORE
Aspirin Capsules, 81 mg Pain Reliever/Fever Reducer (NSAID)

30 Liquid-Filled Capsules

81 mg LOW DOSE

DO NOT USE IF IMPRINTED SAFETY SEAL WITH REPEATED TEXT "SEALED FOR YOUR PROTECTION" UNDER CAP IS MISSING OR BROKEN
See carton for complete warnings and information.

Uses

For the temporary relief of minor aches and pains associated with headache, backache, muscular aches, a cold, toothache, minor pain of arthritis, premenstrual and menstrual cramps. Temporarily reduces fever. Ask your doctor about other uses for aspirin capsules.

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include hives, facial swelling, shock and asthma (wheezing). This product contains soy.

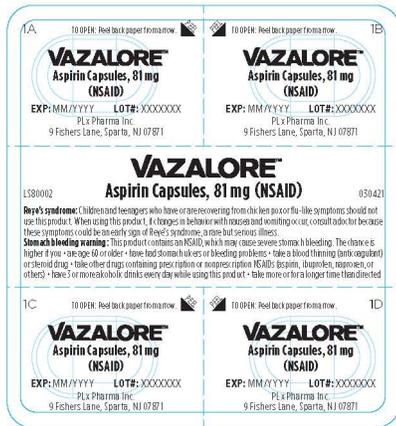
027543

LOT

EXP

PEEL

4 Count Blister Card



VAZALORE
Aspirin Capsules, 81 mg (NSAID)

EXP: MM/YYYY LOT#: XXXXXXXX
PLX Pharma Inc.
9 Fishers Lane, Sparta, NJ 07871

VAZALORE
Aspirin Capsules, 81 mg (NSAID)

EXP: MM/YYYY LOT#: XXXXXXXX
PLX Pharma Inc.
9 Fishers Lane, Sparta, NJ 07871

VAZALORE
Aspirin Capsules, 81 mg (NSAID)

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Aspirin Capsules, 81 mg (NSAID)

EXP: MM/YYYY LOT#: XXXXXXXX
PLX Pharma Inc.
9 Fishers Lane, Sparta, NJ 07871

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others); take 3 or more alcoholic drinks every day while using this product; take more or for a longer time than directed.

Drug Facts Label	Size
Drug Facts Title	NA
Drug Facts Continued	NA
Headings	NA
Subheadings	6 pt
Body Text	6 pt
Leading	6 pt
Characters Per Inch	<45
Bullets	NA
Space Before Bullet	NA
Barlines	NA
Hairlines	NA

4 Count Blister Carton

Drug Facts Label	Size
Drug Facts Title	11 pt
Drug Facts Continued	8 pt
Headings	8 pt
Subheadings	6 pt
Body Text	6 pt
Leading	6.5 pt
Characters Per Inch	<39
Bullets	5 pt
Space Before Bullet	2 ems
Barlines	1.5 pt
Hairlines	.33 pt



12 Count Blister Carton

Drug Facts Label	Size
Drug Facts Title	11 pt
Drug Facts Continued	8 pt
Headings	8 pt
Subheadings	6 pt
Body Text	6 pt
Leading	6.5 pt
Characters Per Inch	<39
Bullets	5 pt
Space Before Bullet	2 ems
Barlines	1.5 pt
Hairlines	.33 pt



aspirin capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73089-081
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg in 81 mg

Inactive Ingredients

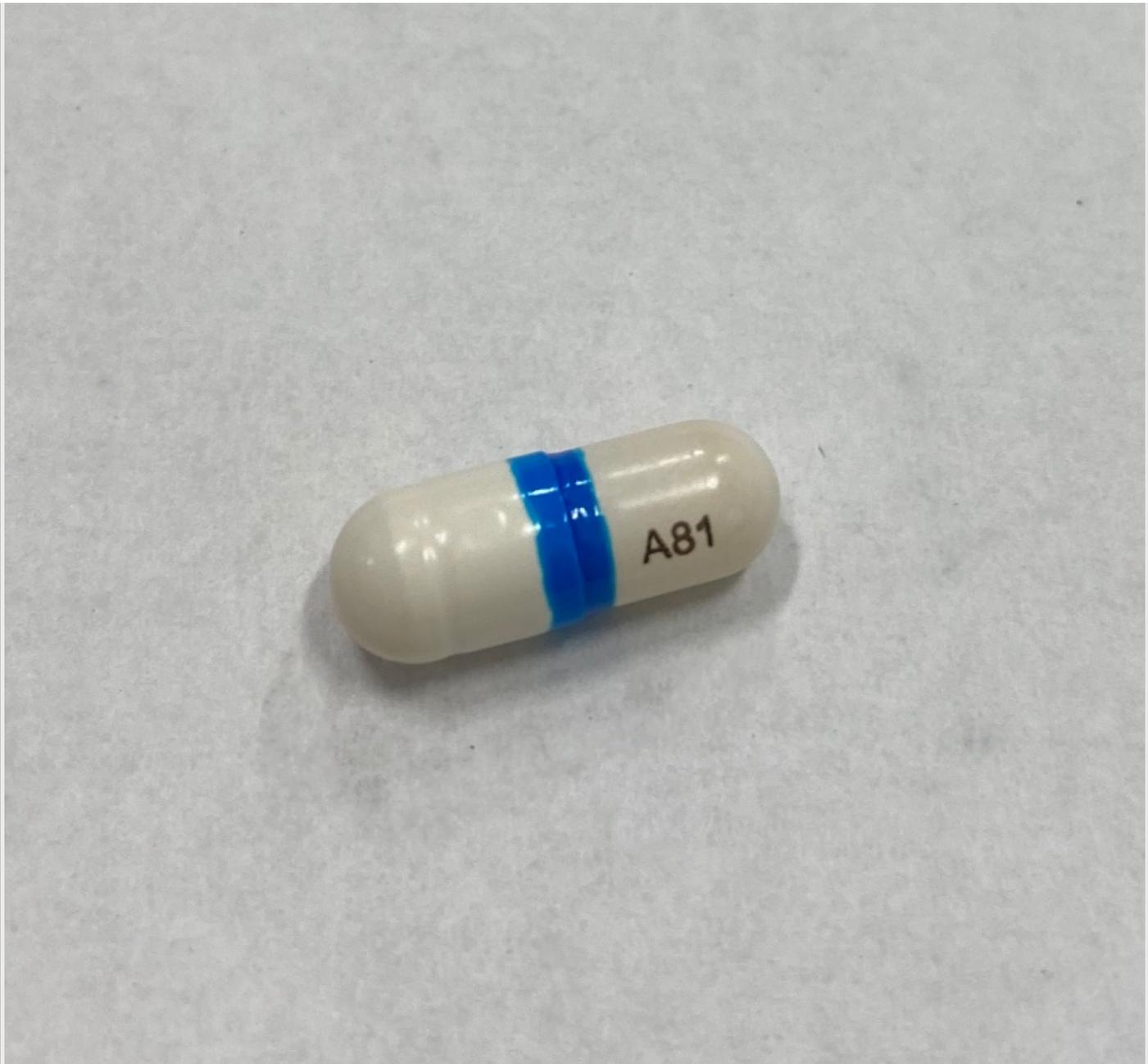
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
OLEIC ACID (UNII: 2UMI9U37CP)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SOYBEAN OIL (UNII: 241ATL177A)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (White with Blue Band and A81 Imprint)	Score	no score
Shape	CAPSULE (White Capsule with Blue Band and A81 Imprint)	Size	14mm
Flavor		Imprint Code	A81
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73089-081-21	1 in 1 CARTON	08/05/2021	
1		81 mg in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:73089-081-12	1 in 1 CARTON	08/05/2021	
2		81 mg in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:73089-081-14	81 mg in 1 CARTON; Type 0: Not a Combination Product	08/05/2021	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA203697	08/05/2021	

Labeler - PLx Pharma Inc (079325568)

Registrant - PLx Pharma Inc (079325568)