

ASPIRIN- aspirin tablet
Richmond Pharmaceuticals, Inc.

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.

ENTERIC COATED ASPIRIN 81mg

Active Ingredient

(in each tablet)

Aspirin 81 mg (NSAID) *

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever

Uses

- temporarily relieves minor aches and pains
- for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur.

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
- asthma (wheezing)
- shock
- facial swelling

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 (ibuprofen, naproxen, others)
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product.

Do not use

- if you have ever had an allergic reaction to any other pain reliever / fever reducer

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
- **Ask a doctor or pharmacist before use if you are**
- taking a prescription drug for diabetes, gout or arthritis
- taking any other drug
- under a doctor's care for any serious condition

Stop use and ask a doctor if

- you experiences 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 more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- ringing in the ears or a loss of hearing occurs

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.

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

Directions

DRINK A FULL GLASS OF WATER WITH EACH DOSE

- **adults and children 12 years and older** : take 4 to 8 tablets every 4 hours while symptoms last, but not more than 48 tablets in 24 hours.
- **Children under 12 years** : ask a doctor

Other Information

- store at 15-30 °C (59-86 °F)

Inactive Ingredients

croscarmellose sodium, D&C Yellow #10 (Al-Lake), HPMC, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, propylene glycol, PVP, silicon dioxide, sodium lauryl sulfate, corn starch, stearic acid, talc, titanium dioxide

Questions or Comments

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Safer for your stomach than pain or Buffered Aspirin

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 54738-559-12– 120 Tablets

*Compare to active ingredient in BAYER® Adult Low Strength Enteric Coated Aspirin

NDC 54738-559-12

SEE NEW WARNINGS INFORMATION

Enteric Coated ASPIRIN (NSAID)
81 mg
Adult Low Strength Pain Reliever
120 TABLETS

Richmond Pharmaceuticals, Inc.

Drug Facts
Active ingredient (in each tablet) Purpose
Aspirin 81 mg (NSAID) Pain reliever
*nonsteroidal anti-inflammatory drug

Uses ■ temporarily relieves minor aches and pains
■ for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur.

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 ■ asthma (wheezing) ■ shock

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 non-prescription NSAIDs (ibuprofen, naproxen, or others)
■ take more or for a longer time than directed
■ have 3 or more alcoholic drinks every day while using this product.

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

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
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Richmond, VA 23223, USA

Let No.:
Exp. Date:

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PEEL HERE FOR MORE DRUG FACTS

LR1114

Drug Facts (continued)

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

Ask a doctor or pharmacist before use if you are
■ taking a prescription drug for diabetes, gout or arthritis
■ under a doctor's care for any serious condition
■ taking any other drug

Stop use and ask a doctor if
■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood
■ have bloody or black stools
■ pain gets worse or lasts more than 10 days
■ fever gets worse or lasts more than 3 days
■ redness or swelling is present in the painful area
■ any new symptoms appear
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■ **children under 12 years:** ask a doctor

Other information
■ store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients croscarmellose sodium, D&C yellow #10 (AI-100), HPMC, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, polyethylene glycol, PVP, silicon dioxide, sodium lauryl sulfate, corn starch, stearic acid, talc, titanium dioxide

Questions or comments?
call 800-270-4488, 8:30 am-4:30 pm ET, Monday - Friday

NDC: 54738-559-25 - 240 Tablets

NDC: 54738-559-03 - 1000 Tablets

ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54738-559
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	AP;121
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-559-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2015	
2	NDC:54738-559-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2015	
3	NDC:54738-559-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	04/01/2015	

Labeler - Richmond Pharmaceuticals, Inc. (043569607)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-559)