

CARDIASPIRIN PROTECT- aspirin tablet, 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.

CARDIASPIRIN PROTECT

Drug Facts

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID) ¹

¹ nonsteroidal anti-inflammatory drug

Purpose

Active ingredient (in each tablet)

Aspirin 81mg (NSAID)*

Purpose

Pain reliever

*nonsteroidal ant-inflammatory drug

Uses

- temporarily relief of minor aches and pains or as recommended by your doctor.
Because of its delayed release action, this product will not provide fast relief of headache or symptoms needing immediate relief.

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
- shock
- facial swelling

- asthma (wheezing)

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

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor or pharmacist before use if

- you have asthma
- 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

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, have bloody or black stools, vomit blood, have stomach pain that does not get better.
- an allergic reaction occurs.
- Seek medical help right away.
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

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 (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

- drink a full glass of water with each dose
-
- adults and children 12 years and over:
- take 4 to 8 tablets every 4 hours while symptoms lasts.
 - do not take more than 48 tablets in 24 hours unless directed by a doctor
- children under 12 years:
- ask a doctor
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Other information

- store at room temperature 15-30 °C (59-86 °F)
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

Anhydrous Lactose, Carnuba Wax, Colloidal Silicon Dioxide, Crosscarmellose Sodium, FD&C Yellow #10 al lake, FD&C Yellow#6 al Lake, Iron Oxide Ochre, Methacrylic acid copolymer, Microcrystalline cellulose, Polysorbate 80, simethiocone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments?

call toll free Call (619) 600-5632

Monday through Friday 9AM - 5PM EST

Cardiaspirin Protect Label

NDC 69729-104-12

CARDIASPIRIN PROTECT

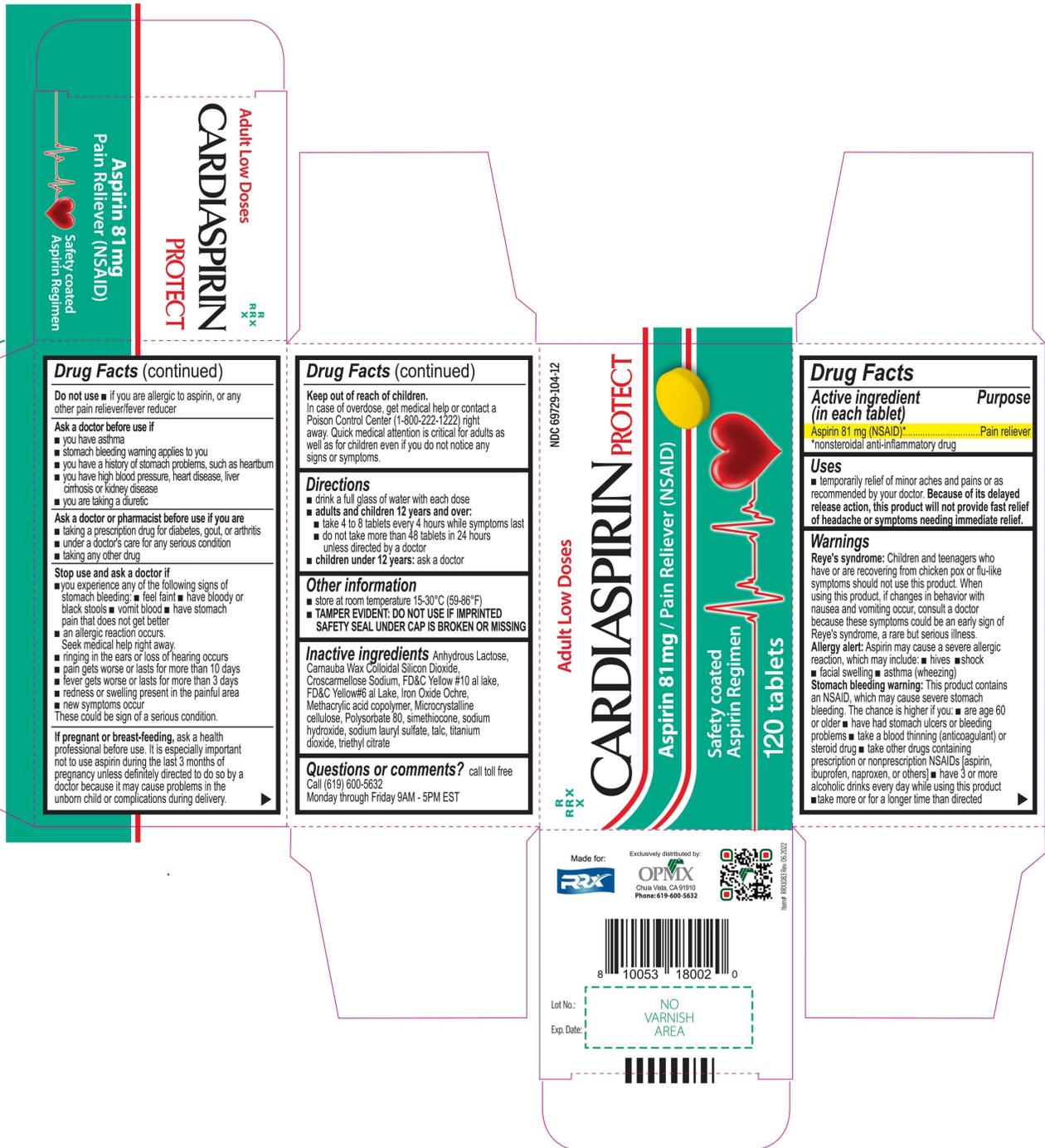
Adult Low Doses

Aspirin 81mg/ Pain Reliever (NSAID)

Safety Coated

Aspirin Regimen

120 tablets



CARDIASPIRIN PROTECT

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-104
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
TALC (UNII: 7SEV7J4R1U)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	A1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-104-12	1 in 1 CARTON	08/21/2023	
1		120 in 1 BOTTLE, PLASTIC; 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	08/21/2023	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	label(69729-104) , manufacture(69729-104) , pack(69729-104)

Revised: 8/2023

OPMX LLC