

ASPIRIN- aspirin tablet, coated
TARGET CORPORATION

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.

481R-TARGET - LOW DOSE ASPIRIN 81 MG DELAYED RELEASE 11673-181

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains **Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.**
- ask your doctor about other uses for enteric-coated 81 mg Aspirin

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)

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 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
- you have not been drinking fluids
- you have lost a lot of fluid due to vomiting or diarrhea

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

- an allergic reaction occurs. Seek medical help right away
- 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

- pain gets worse or lasts more than to days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

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 right away.

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 not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

OTHER INFORMATION

Other information

- store at 25°C (77°F) excursions permitted between 15°-30°(59°-86°F)
- use by expiration date on package

Inactive ingredients anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow no.10, aluminium lake, iron oxide ochre, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate starch, talc, titanium dioxide, triethyl citrate


Questions? Call 1-800-910-6874



NDC 11673-181-12

low-dose aspirin

81 mg delayed-release tablets pain reliever (NSAID)



safety coated aspirin regimen

120 ENTERIC-COATED TABLETS

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Uses ■ temporarily relieves minor aches and pains
Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.
 ■ ask your doctor about other uses for enteric-coated 81 mg Aspirin

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) **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

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 over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
 ■ children under 12 years: consult a doctor

Other information ■ **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING** ■ use by expiration date on package **Questions? Call 1-800-910-6874 (777)** excursions permitted between 15°-30°C (59°-86°F) ■ use by expiration date on package

094 01 0362 R00 C-001227-01-033
 Dist. by Target Corp., Minneapolis, MN 55403 TM & ©2020 Target Brands, Inc.
 481RR 0819
 Lot No.:
 Exp. Date:

NDC 11673-181-50
Compare to active ingredient in Bayer® Low Dose Aspirin®

low-dose aspirin

81 mg delayed-release tablets
pain reliever (NSAID)



safety coated aspirin regimen



ACTUAL SIZE

500 TABLETS

500 ENTERIC-COATED TABLETS

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

Active ingredient (in each tablet)
Aspirin 81 mg (NSAID)*

Purpose
*nonsteroidal anti-inflammatory drug
Pain reliever

Uses

- for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.
- ask your doctor about other uses for enteric-coated 81 mg Aspirin

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)

Drug Facts (continued under label)

Questions? Call 1-800-910-6874

Dist. by Target Corp., Minneapolis, MN 55403

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*This product is not manufactured

or distributed by 084 01 0678 R01 C-001227-01-033

Bayer HealthCare LLC,

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Low Dose,

481R 0521



Lot No. UNVARNISHED AREA Exp Date.

Drug Facts (continued)

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
- if you have ever had an allergic reaction to this product or any of its ingredients

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:

- allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - stools
 - blood in stool
 - more bloody or black stools
 - vomit blood
 - 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
- ringing in the ears or a loss of hearing occurs

Drug Facts (continued)

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 over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat above 40°C (104°F)
- use by expiration date on package

Inactive ingredients

anhydrous lactose, croscarmellose sodium, D1C yellow colloidal silicon dioxide, croscarmellose sodium, D1C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, poly sorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

ASPIRIN

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-181
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
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)		
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
STARCH, CORN (UNII: O8232NY3SJ)		
TALC (UNII: 7SEV7J4R1U)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		

Product Characteristics			
Color	yellow	Score	no score
Shape	ROUND (bi-convex)	Size	7mm
Flavor		Imprint Code	HEART;RAISED
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-181-12	1 in 1 CARTON	01/01/2020	
1		120 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:11673-181-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/2020	

Labeler - TARGET CORPORATION (006961700)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(11673-181)

Revised: 8/2021

TARGET CORPORATION