

LOW DOSE ASPIRIN- aspirin tablet, coated
TIME CAP LABORATORIES, INC

481R TCL 49483-481 ASPIRIN 81MG DELAYED RELEASE TABLETS

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

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
- 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 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

- you have asthma
- stomach bleeding warning applies to you

- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug for:

- gout
- diabetes
- arthritis

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 more than 3 days
- redness or swelling is present
- new symptoms occur
- 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 (1-800-222-1222) 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°C (59°-86°F)
- use by expiration date on package
- avoid excessive heat above 40°C (104°F)

Inactive ingredients anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum 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

Drug Facts (continued)

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

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- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
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Ask a doctor or pharmacist before use if you are taking a prescription drug for:

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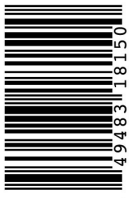
Inactive ingredients

amylotrioxycellulose, carmellose, colloidal silicon dioxide, croscarmellose sodium, D&G 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

Questions or comments? Call 1-877-290-4008

Adhesive Area

Varnish Omit Area



PEEL HERE
LOT:
EXP:

Drug Facts (continued under label)

This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Low Dose Aspirin

Manufactured by:

Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale,
NY 11735
Made in U.S.A.
481R 1223

- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- cause severe stomach bleeding. The chance is higher if you:

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- have had stomach ulcers or bleeding problems
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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.

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- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

NDC 49483-481-50
Compare to the active ingredient in Bayer® Low Dose Aspirin^{††}



ASPIRIN
81 mg Delayed-Release Tablets
Pain Reliever (NSAID)

LOW DOSE
Safety Coated | Aspirin Regimen

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)* Pain reliever
*nonsteroidal anti-inflammatory drug

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.

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Drug Facts (continued under label)

This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Low Dose Aspirin

Manufactured by:

Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale,
NY 11735
Made in U.S.A.
481R 1223

PEEL HERE
LOT:
EXP:

Adhesive Area

Drug Facts (continued)

Ask a doctor before use if

- you have asthma
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug for: ■ gout ■ diabetes ■ arthritis

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:
 - 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
- new symptoms occur
- 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 (1-800-222-1222), 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)
- see by expiration date on package
- avoid excessive heat above 40°C (104°F)

Inactive ingredients anhydrous lactose, carnuba wax, colloidal silicon dioxide, croscarmellose sodium, D&E 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

Questions or comments? Call 1-877-290-4008

NDC 49483-481-10

Compare to the active ingredient in Bayer® Low Dose Aspirin††



ASPIRIN
81 mg Delayed-Release Tablets
Pain Reliever (NSAID)

LOW DOSE
Safety Coated | Aspirin Regimen

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

1000 ENTERIC COATED TABLETS

Actual Size

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
Pain reliever
*nonsteroidal anti-inflammatory drug

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.

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■ 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

Drug Facts (continued under label)

††This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer®

Manufactured by:
Time-Cap Labs, Inc. 7 Michal
Avenue Farmingdale, NY 11735
Made in U.S.A.
481R 0123



LOT #: _____
EXP. DATE: _____

Varnish Omit Area

PEEL HERE

NDC 49483-481-31
compare to the active ingredient
in Bayer® Low Dose


timely™

ASPIRIN

81 mg Delayed-Release Tablets
Pain Reliever
(NSAID)

LOW DOSE
Safety Coated | Aspirin Regimen

300
ENTERIC COATED
TABLETS

 Actual Size

STOP PEELING

Drug Facts

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

Purpose
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


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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

Drug Facts (continued under label)

This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose. Manufactured by: Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, NY 11735 481R 0421

LOT #: 4948314813100
EXP. DATE:

PEEL HERE 

LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-481
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

Drug Facts (continued)
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: ■ diabetes ■ gout ■ arthritis

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 10 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ 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 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) ■ use by expiration date on package ■ avoid excessive heat above 40°C (104°F)

Inactive ingredients amygdricous lactose, carnaluba wax, colloidal silicon dioxide, croscarmellose sodium, D&G yellow #10 aluminum lake, iron oxide orange, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyacrylate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

Questions? Call 1-877-290-4008

STOP PEELING

Ingredient Name	Strength
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-481-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2015	
2	NDC:49483-481-12	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2015	
3	NDC:49483-481-00	1000000 in 1 CARTON; Type 0: Not a Combination Product	06/19/2015	
4	NDC:49483-481-31	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2021	
5	NDC:49483-481-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2021	
6	NDC:49483-481-65	365 in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/19/2015	

Labeler - TIME CAP LABORATORIES, INC (037052099)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(49483-481)

Revised: 12/2023

TIME CAP LABORATORIES, INC