

LOW DOSE ASPIRIN- aspirin tablet, coated

Topco Associates

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.

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 safety 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.
- if you have ever had an allergic reaction to his 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

- 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 stool
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever get worse or lasts more than 3 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs
- 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 at during the last 3 month 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 between 15-30°C (59-86°F)

Inactive ingredients

croscarmellose sodium, D&C yellow #10, lactose monohydrate, methacrylic acid, microcrystalline cellulose 102, polacrillin potassium, polyethylene glycol 6000, polyvinyl alcohol, purified talc, silicon dioxide, sodium lauryl sulfate, soybean, titanium dioxide, triethyl citrate

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

COMPARE TO BAYER® LOW DOSE ASPIRIN ACTIVE INGREDIENT≠

LOW DOSE

ASPIRIN REGIMEN

Aspirin 81 mg

PAIN RELIEVER (**NSAID**)

Safety Coated††

TABLETS

†Talk to your doctor or other healthcare provider before using this product for your heart. Aspirin is not right for everyone.

††Coating helps protect against stomach upset

≠This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer® Low Dose Aspirin.

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

DISTRIBUTED BY

TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

Product Label

NDC 76162-980-05

TopCare
health

COMPARE TO BAYER® LOW DOSE ASPIRIN ACTIVE INGREDIENT†

LOW DOSE ♥
ASPIRIN REGIMEN*
Aspirin 81 mg
PAIN RELIEVER (NSAID)
Safety Coated EASY OPEN CAP**

†Talk to your doctor or other healthcare provider before using this product for your heart. Aspirin is not right for everyone.
**Coating helps protect against stomach upset

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

500 TABLETS actual size

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 safety. Each 81 mg aspirin tablet contains 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
swelling of the face
rash
difficulty breathing
stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
take aspirin for a long time or for a longer time than directed
take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
take blood thinning (anticoagulant) or steroid drugs
take 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 you have ever had an allergic reaction to this product or any of its ingredients
you have a history of stomach problems, such as heartburn
stomach bleeding warning applies to you

Drug Facts (continued under label)
This product is not manufactured or distributed by Bayer HealthCare, a division of Bayer, Low Dose Aspirin.
NSC 107030
EPA REG. NO. 149-032
NDC 76162-980-05
LOT 16007
MFG. DATE 03/15/15
www.topcarehealth.com
Visit here for more information:
<http://topcare.com/4962to>
Exp. Date: 03/2018
NDC 76162-980-05
36800 16593 9
Lot No.: 0383803
PEEL HERE

Drug Facts (continued)

- 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: 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
- ringing in the ears or loss of hearing occurs
- 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.

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 between 15-30°C (59-86°F)

Inactive ingredients: croscarmellose sodium, D&C yellow #10, lactose monohydrate, methacrylic acid, microcrystalline cellulose 102, polyacrylamide, polyethylene glycol 6000, polyvinyl alcohol, purified talc, silicon dioxide, sodium lauryl sulfate, soybean, titanium dioxide, triethyl citrate

Questions or comments?
Call toll free 1-888-423-0139

TOPCARE HEALTH Low Dose Aspirin 81 mg

LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-980
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
METHACRYLIC ACID (UNII: 1CS02G8656)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)
SOYBEAN (UNII: L7HT8F1ZOD)
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	P
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-980-50	1 in 1 BOX	08/01/2023	
1		500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:76162-980-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2023	
3	NDC:76162-980-12	1 in 1 BOX	08/01/2023	
3		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 final	part343	08/01/2023	

Labeler - Topco Associates (006935977)