

ASPIRIN- aspirin tablet, delayed release
Topco Associates, LLC

TopCare 44-227-Delisted

Active ingredient (in each tablet)

Aspirin 325 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.

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

- 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
- 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 have asthma
- you are taking a diuretic

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
- ringing in the ears or a loss of hearing occurs
- new symptoms occur
- pain gets worse or lasts more than 10 days
- redness or swelling is present

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 1 to 2 tablets every 4 hours not to exceed 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: do not use unless directed by a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

black iron oxide, cellulose, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, shellac wax, simethicone, sodium alginate, sodium bicarbonate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-888-423-0139

Principal Display Panel

**TopCare®
health**

NDC 36800-127-57

COMPARE TO ECOTRIN® REGULAR STRENGTH
ACTIVE INGREDIENT†

REGULAR STRENGTH ASPIRIN REGIMEN††

Aspirin 325 mg
Pain reliever (**NSAID**)

Safety Coated

††Talk to your doctor or other healthcare provider before using this product for your heart.

125 ENTERIC COATED TABLETS

Actual Size

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

©TOPCO LNKA0221

QUESTIONS? 1-888-423-0139

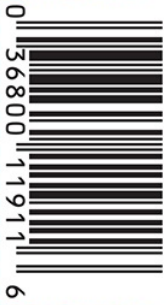
topcare@topco.com www.topcarebrand.com

QUALITY GUARANTEED

†This product is not manufactured or distributed by Medtech Products Inc., owner of the registered trademark Ecotrin® Regular Strength.

50844 ORG031822757

No Print / No Varnish
Lot no. & Exp. date



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

B-1910-227-57
ORG031822757

Drug Facts
Active ingredient (in each tablet)
Aspirin 325 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.

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

TopCare health

COMPARE TO ECOTRIN® REGULAR STRENGTH ACTIVE INGREDIENT*

REGULAR STRENGTH ASPIRIN REGIMEN**

Aspirin 325 mg

PAIN RELIEVER (NSAID)
Safety Coated

††Talk to your doctor or other healthcare provider before using this product for your heart.

125 ENTERIC COATED TABLETS actual size

TopCare health

REGULAR STRENGTH ASPIRIN REGIMEN**

Aspirin 325 mg

PAIN RELIEVER (NSAID)

125 ENTERIC COATED TABLETS

Drug Facts (continued)

Directions
■ drink a full glass of water with each dose
■ adults and children 12 years and over: take 1 to 2 tablets every 4 hours not to exceed 12 tablets in 24 hours unless directed by a doctor
■ children under 12 years: do not use unless directed by a doctor

Other information
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
■ see end flap for expiration date and lot number

Inactive ingredients black iron oxide, cellulose, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, stearic acid, sodium alginate, sodium bicarbonate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO L1K40221
topcare@topco.com www.topcarebrand.com

Scan here for more information or call 1-888-423-0139

QUALITY GUARANTEED
This product is not manufactured or distributed by Mediatech Products Inc., owner of the registered trademark Ecotrin® Regular Strength.
50844 - ORG031822757

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
■ stomach bleeding warning applies to you
■ you have a history of stomach problems, such as heartburn
■ you have asthma
■ 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
■ 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:
■ vomit blood ■ have bloody or black stools
■ ringing in the ears or a loss of hearing occurs
■ new symptoms occur
■ pain gets worse or lasts more than 10 days
■ redness or swelling is present
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.

44-227

ASPIRIN aspirin tablet, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-127
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	325 mg	
Inactive Ingredients				
Ingredient Name		Strength		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)				
POWDERED CELLULOSE (UNII: SMD1X3XO9M)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SHELLAC (UNII: 46N107B71O)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
WATER (UNII: 059QF0KO0R)				
SODIUM ALGINATE (UNII: C269C4G2ZQ)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIACETIN (UNII: XHX3C3X673)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	44;227	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-127-57	1 in 1 CARTON	04/13/2021	04/05/2025
1		125 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 Drug	M013	04/13/2021	04/05/2025
--------------------	------	------------	------------

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(36800-127) , pack(36800-127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(36800-127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(36800-127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(36800-127)