

ASPIRIN LOW DOSE- aspirin tablet, coated
Rugby Laboratories

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.

Rugby 44-600A

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.**

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 more or for a longer time than directed
- 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

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:
 - vomit blood
 - have bloody or black stools
 - feel faint
 - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 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.

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: 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

corn starch, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-645-2158

Principal Display Panel

Rugby®

NDC 0536-1234-41

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

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

Low Dose

Aspirin 81 mg

Pain Reliever (NSAID)

Aspirin Regimen

Safety Coated

Actual Size

120 Enteric Coated Tablets

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

Rev. 05/19 R-17 Re-order No. 370718

[†]This product is not manufactured or distributed by Bayer
AG, owner of the registered trademark Bayer® Low Dose
Aspirin. 50844 ORG031860032

Distributed by: Rugby Laboratories

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

No print/No varnish
Lot & Exp date

3 05361 23441 6

Rev. 05/19 R-17 Re-order No. 370718

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KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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Low Dose Aspirin 81 mg Pain Reliever (NSAID) Aspirin Regimen

120 Enteric Coated Tablets

Safety Coated Actual Size

Drug Facts (continued)
Questions or comments?
1-800-645-2158

This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Low Dose Aspirin, 50844 ORG031860032
Distributed by: Rugby Laboratories
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
www.rugbylaboratories.com

B-1212-600A-32-RU
ORG031860032

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Drug Facts (continued)

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Rugby 44-600A

ASPIRIN LOW DOSE			
aspirin tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1234
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	6 mm
Flavor		Imprint Code	L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1234-41	1 in 1 CARTON	07/01/2019	
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	07/01/2019	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(0536-1234) , PACK(0536-1234)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0536-1234)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0536-1234)

Revised: 5/2020

Rugby Laboratories