# RUGBY ADULT ASPIRIN- as pirin tablet, film 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.

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## **Rugby Laboratories Adult Aspirin Drug Facts**

#### Active ingredient (in each tablet)

Aspirin 325 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

## **Purposes**

Pain reliever/fever reducer

#### Uses

temporarily relieves

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
- minor pain of arthritis

#### 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 have ever had an allergic reaction to 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

#### 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
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- 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 (1-800-222-1222).

#### **Directions**

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 or 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
- children under 12 years: consult a doctor

## Other information

• store at 20°-25°C (68°-77°F)

## **Inactive ingredients**

corn starch, dibasic calcium phosphate dihydrate, hypromellose, talc, triacetin

## Questions or comments?

1-800-645-2158

## **Principal Display Panel**

Compare to active ingredient in Bayer<sup>®</sup> Aspirin

Adult Aspirin 325 mg

Pain Reliever/Fever Reducer (NSAID)

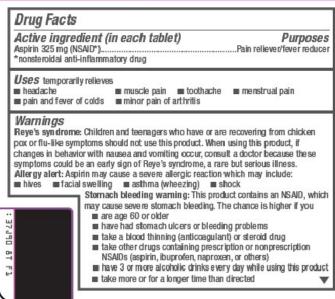
Talk to your doctor or other healthcare provider before using this product for your heart.

**Actual Size** 

500 Coated Tablets

PEEL BACK HERE





#### Drug Facts (continued)

Do not use if you have ever had an allergic reaction to any other pain reliever/

#### 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

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\*\*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer® Aspirin.

#### **RUGBY ADULT ASPIRIN**

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1284
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	
STARCH, CORN (UNII: O8232NY3SJ)		
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)		
TALC (UNII: 7SEV7J4R1U)		
TRIACETIN (UNII: XHX3C3X673)		

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	L37J
Contains			

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0536-1284-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	
2	NDC:0536-1284-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	03/09/2020		

## Labeler - Rugby Laboratories (079246066)

Revised: 3/2020 Rugby Laboratories