

BUFFERIN- aspirin tablet
Dr. Reddy's Laboratories Inc.

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.

Bufferin®

Drug Facts

Active ingredient (in each tablet)

Buffered aspirin equal to 325 mg aspirin (NSAID)¹ (buffered with magnesium carbonate, calcium carbonate and magnesium oxide)

¹ nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains associated with:
 - headache
 - minor pain of arthritis
 - backache
 - toothache
 - the common cold
 - muscular aches
 - premenstrual & menstrual cramps
- temporarily reduces fever

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.

Ask a doctor before use if

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

- 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
- an allergic reaction occurs
- symptoms do not improve
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- 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 (1-800-222-1222) right away.

Directions

- adults and children 12 years and over: 2 tablets with a full glass of water. Dosage may be repeated every 4 hours while symptoms persist. Do not 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

- each tablet contains: **calcium 35 mg** and **magnesium 40 mg**
- 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

citric acid, corn starch, dibasic sodium phosphate, hydrogenated vegetable oil, hypromellose, microcrystalline cellulose, polyethylene glycol, propylene glycol, shellac wax, simethicone, sodium lauryl sulfate, talc, titanium dioxide

Questions or comments?

1-800-790-6417

PRINCIPAL DISPLAY PANEL - 130 Tablet Bottle Box

NDC 55741-013-13

***Tough on pain. Gentler to your stomach.
than plain aspirin****

BUFFERIN®

BUFFERED ASPIRIN (NSAID)

Pain Reliever/Fever Reducer

130 COATED TABLETS

325 mg EACH

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN



BUFFERIN

aspirin tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55741-013

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
citric acid monohydrate (UNII: 2968PHW8QP)	
starch, corn (UNII: O8232NY3SJ)	
Sodium Phosphate, Dibasic (UNII: GR686LBA74)	
hypromelloses (UNII: 3NXW29V3WO)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
propylene glycol (UNII: 6DC9Q167V3)	
sodium lauryl sulfate (UNII: 368GB5141J)	
talc (UNII: 7SEV7J4RIU)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	B
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55741-013-13	1 in 1 BOX	05/24/2016	
1		130 in 1 BOTTLE; 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	05/24/2016	

Labeler - Dr. Reddy's Laboratories Inc. (802315887)