

BUFFERIN ARTHRITIS- 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 Arthritis

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
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

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 - 60 Tablet Bottle Box



LNK International, Inc. 22 Arkay Drive Hauppauge LI, NY 11788 tel. 631.435.3500 fax 631.952.4680	LNK Part#: B-0385-624-11 DF version: 44-624.03 / 0115 Desc.: Bufferin Arthritis 60 count tablets Size: DG97A Proof #: 3rd UPC: 8 49648 00000 9 NDC/Item: N/A Customer: Duocore Pharma Artist: <i>De Emans</i> Create/Rev. Date: 09/14/11 04/04/16 Drug Facts uses more than 60% of the total surface area.	Colors: Dieline (or not print) Duocore (4C Process) RED	DF Title: 10 pt. Headings: 8 pt. Body Text: 6 pt. Loading: 6.3 pt. Bullets: 5 pt. Barlines: 2 pt. Hairlines: 5 pt. Modified Format used CFR201.66 (d)(10)	Horiz. Scale: 80% Bottle Size: 75cc, p/4 IAAA Required Information Most prominent pdp text: 15.81 pt. IAAA active: 9.41 pt. NSAID: 11.13 pt. See new warnings...: N/A	<input type="checkbox"/> Proof Approved <input type="checkbox"/> Approved with Changes <input type="checkbox"/> Reproof Required
	Product Type: <input type="radio"/> Bottle Only <input type="radio"/> Clear Bottle <input type="radio"/> Vial <input type="radio"/> Tray <input type="radio"/> Other _____ (check off all that applies) <input checked="" type="radio"/> Carton & Bottle <input type="radio"/> Blister Box <input type="radio"/> 5th panel <input type="radio"/> Z-Fold <input type="radio"/> Flat Fold				

CUSTOMER IS RESPONSIBLE FOR FINAL PROOF. This proof has been carefully prepared according to our understanding of our specifications and our QASOP procedures. Keep proof attached to disk. **DO NOT APPROVE THIS PROOF ON GENERAL APPEARANCE.** Please examine it carefully for: 1. Customer specific UPC, product item & NDC numbers 2. Company logo & distribution information 3. Spelling, 4. Spacing, 5. Punctuation/Trademarks, 6. Colors. **We do not assume responsibility for errors and/or omissions after printing.**

Tough on pain. Gentler to your stomach.

BUFFERIN® Arthritis

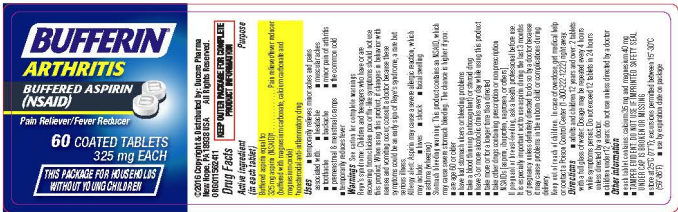
BUFFERED ASPIRIN (NSAID)

Pain Reliever/Fever Reducer

60 COATED TABLETS

325 mg EACH

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN



LNK International, Inc. 22 Arkay Drive Hauppauge LI, NY 11788 tel. 631.435.3500 fax 631.952.4680	LNK Part#: L-0385-624-11 DF version: 44-624.03 / 0115 Desc.: Bufferin Arthritis 60 count tablets Size: 1.5 x 5.125 Proof #: 2nd UPC: TBD NDC Item: TBD Customer: Duocore Pharma Artist: Emma Create/Rev Date: 09/15, 11/13/15 Drug Facts uses more than 60% of the total surface area.	Colors: Die Line Bleed Line DF Title: 7.5 pt. Headings: 5.5 pt. Body Text: 4.5 pt. Leading: 4.7 pt. Bullets: 3.5 pt. Barlines: N/A Hairlines: N/A Horz. Scale: 80% Bottle Size: 756g, p004 IAAA Required Information Most prominent pdp text: pt. IAAA active: NA NSAID: pt. See new warnings...: pt. Modified Format used CFR201.66 (d)(10)	<input type="checkbox"/> Proof Approved <input type="checkbox"/> Approved with Changes <input type="checkbox"/> Reprint Required AI Adobe® Illustrator CS6
Product Type: (check off all that applies) <input checked="" type="checkbox"/> Bottle Only <input type="checkbox"/> Clear Bottle <input type="checkbox"/> Vial <input type="checkbox"/> Tray <input type="checkbox"/> Other <input checked="" type="checkbox"/> Carton & Bottle <input type="checkbox"/> Blister Box <input type="checkbox"/> 5th panel <input type="checkbox"/> Z-Fold <input type="checkbox"/> 5th panel <input type="checkbox"/> Flat Fold			
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BUFFERIN ARTHRITIS

aspirin tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55741-000
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: 7SEV7J4R1U)				
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:55741-000-60	1 in 1 BOX	07/20/2016	
1		60 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		07/20/2016	

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

Revised: 12/2019

Dr. Reddy's Laboratories Inc.