

BUFFERIN REGULAR STRENGTH PAIN RELIEF- aspirin tablet, coated Genomma Lab USA

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® Regular Strength Pain Relief

Drug Facts

Active ingredient (in each tablet)

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

¹ nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains associated with:
 - headache
 - toothache
 - backache
 - muscular aches
 - headache
 - minor pain of arthritis
 - the common cold
 - 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

- 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

- 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 other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- 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 asthma
- 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:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - 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
- fever gets worse or lasts more than 3 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 right away.

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 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

- **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

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

Questions or comments?

1-877-994-3666

Distributed by:

Genomma Lab USA Inc.

Houston, TX 77027

PRINCIPAL DISPLAY PANEL - 325 mg Table Bottle Carton

Regular Strength

Tough on pain. Gentler to your stomach.™

BUFFERIN®

BUFFERED ASPIRIN (NSAID)

Pain Reliever

Fever Reducer

30 Coated Tablets 325 mg each

No Print/No Varnish
Lot & Expiry Area

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

Drug Facts (continued)

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- new symptoms occur

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Inactive ingredients: anhydrous citric acid, corn starch, dibasic sodium phosphate anhydrous, hydrogranulated vegetable oil, hypromellose, microcrystalline cellulose, polyethylene glycol.

Drug Facts (continued)

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Drug Facts (continued)

propylene glycol, shellac wax, simethicone, sodium lauryl sulfate, talc, titanium dioxide

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Genomma Lab USA Inc.
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2000010869

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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Regular Strength

Tough on pain. Gentler to your stomach.™

BUFFERIN

BUFFERED ASPIRIN (NSAID)

Pain Reliever
Fever Reducer

30 Coated Tablets 325 mg each

DG9146A

B-0695-624-01
OHG

BUFFERIN REGULAR STRENGTH PAIN RELIEF

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-610
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
calcium carbonate (UNII: H0G9379FGK)	
magnesium carbonate (UNII: 0E53J927NA)	
magnesium oxide (UNII: 3A3U0GI71G)	
anhydrous citric acid (UNII: XF417D3PSL)	
Propylene glycol (UNII: 6DC9Q167V3)	
microcrystalline cellulose (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-610-13	1 in 1 CARTON	05/17/2021	
1		130 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50066-610-30	1 in 1 CARTON	05/17/2021	
2		30 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	05/17/2021	

Labeler - Genomma Lab USA (832323534)