TRI-BUFFERED ASPIRIN- aspirin tablet, film coated Proficient Rx LP

Major 44-183

Active ingredient (in each tablet)

Buffered aspirin equal to 325 mg aspirin (NSAID)* (buffered with calcium carbonate, magnesium carbonate, and magnesium oxide) *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

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

have had stomach ulcers or bleeding problems

- have 3 or more alcoholic drinks every day while using this product
- are age 60 or older
- take a blood thinning (anticoagulant) or steroid drug
- 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 a history of stomach problems, such as heartburn
- you have asthma
- 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
- arthritis
- diabetes

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:
 - o feel faint
 - o vomit blood
 - o have bloody or black stools
 - o 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 (1-800-222-1222) 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?

(800) 616-2471

Principal Display Panel

NDC 71205-517-30

Compare to the active ingredient in BUFFERIN®†

TRI-BUFFERED ASPIRIN 325 mg

pain reliever/fever reducer (NSAID)

30 TABLETS

 † This product is not manufactured or distributed by Dr. Reddy's Laboratories Inc., owner of the registered trademark Bufferin $^{@}$. 50844 REV0318M18312

Distributed by **MAJOR**® **PHARMACEUTICALS** 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA

Repackaged by **Proficient Rx LP**

M-17

Re-order No. 700594 Rev. 07/18

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





NDC 71205-517-30

Packaged By: Proficient Rx LP Thousand Oaks, CA 91320

Aspirin 325mg #30 Tablets Lot #:00000 SN# MASTER NDC 71205-517-30 Exp:00/00/00

Aspirin 325mg #30 Tablets Lot #:00000 SN# MASTER NDC 71205-517-30 Exp:00/00/00

Aspirin 325mg #30 Tablets Lot #:00000 SN# MASTER

NDC 71205-517-30 Exp:00/00/00

GTIN: 00371205517304

GTIN: 003712055 SN# MASTER Exp. 00/00/00 Lot #:00000

Aspirin 325mg

#30 Tablets

Each tablet contains: Buffered aspirin equal to 325 mg aspirin (NSAID)* Pain reliever/ fever reducer (buffered with calcium carbonate, magnesium carbonate, and magnesium oxide) *nonsteroidal anti-inflammatory drug

White, round, unscored tablet with imprint code "44" and "183"

Product ID: QA051730

Dist. By: MAJOR® PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA

Store at 25°C (77°F)

Keep medication out of the reach of children

TRI-BUFFERED ASPIRIN

aspirin tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71205-517(NDC:0904-2015)

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		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
DIMETHICONE 410 (UNII: TYU5GP6XGE)			

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

SHELLAC (UNII: 46N107B71O)

STARCH, CORN (UNII: 08232NY3SJ)

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	44;183
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205- 517-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2020	
2	NDC:71205- 517-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2020	
3	NDC:71205- 517-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	03/30/1990		

Labeler - Proficient Rx LP (079196022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Proficient Rx LP		079196022	REPACK(71205-517), RELABEL(71205-517)	

Revised: 10/2023 Proficient Rx LP