BAYER RAPID RELIEF- aspirin/caffeine oral powder powder
Bayer HealthCare LLC.

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.

Bayer ® Rapid Relief

Drug Facts

Active ingredient (in each tablet)

Aspirin 650 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Pain reliever aid

Uses

temporarily relieves minor aches and pains due to: • headache • muscle pain • backache • menstrual cramps • minor pain of arthritis • temporarily reduces feve

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 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 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 ● fever gets worse or lasts more than 3 days ● redness or swelling is present ● new symptoms occur ● ringing in the ears or a loss of hearing occurs If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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

adults and children 12 years and over: take contents of 1 powder pack every 6 hours. Dissolve powder on tongue, followed by a full glass of water. Do not exceed 4 powder packs in 24 hours. ● children under 12 years: consult a doctor

Other information

● phenylketonurics: contains phenylalanine 0.0017 mg per powder pack ● save carton for full directions and warnings ● Store between 20°- 25 °C (68°-77° F)

Inactive Ingredients

anhydrous citric acid, flavors, mannitol, neotame, sodium citrate monobasic, sucralose

Questions or comments?

1-800-331-4536 (Mon-Fri 9AM - 5PMEST)

BAYER RAPID RELIEF

aspirin/caffeine oral powder powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0103
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	650 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MANNITOL (UNII: 3OWL53L36A)	

NEOTAME (UNII: VJ597D52EX)	
MONOSODIUM CITRATE (UNII: 68538UP9SE)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0103-01	1 in 1 CARTON	01/13/2023	
1		10 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0280-0103-02	1 in 1 CARTON	01/13/2023	
2		20 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0280-0103-03	1 in 1 CARTON	01/13/2023	
3		30 in 1 PACKET; 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	01/13/2023	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 1/2023 Bayer HealthCare LLC.