

Attachment

Drug Facts

Active ingredients (in each caplet)	Purpose
Buffered aspirin 500 mg	Pain reliever
Use ■ treats the mild to moderate pain of migraine headache	
Warnings	
Reye's syndrome: Children and teenagers should not use this drug for chicken pox, or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.	
Allergy alert: Aspirin may cause a severe allergic reaction which may include:	
■ hives ■ facial swelling ■ asthma (wheezing) ■ shock	
Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.	
Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer	
Ask a doctor before use if you have	
■ never had migraines diagnosed by a health professional ■ a headache that is different from your usual migraines ■ the worst headache of your life ■ fever and stiff neck ■ headaches beginning after or caused by head injury, exertion, coughing or bending ■ experienced your first headache after the age of 50 ■ daily headaches ■ a migraine headache so severe as to require bed rest ■ asthma ■ bleeding problems ■ ulcers ■ stomach problems such as heartburn, upset stomach, or stomach pain that do not go away or recur ■ problems or serious side effects from taking pain reliever/fever reducers ■ vomiting with your migraine headache	
Ask a doctor or pharmacist before use if you are	
■ taking a prescription drug for: ■ anticoagulation (thinning of the blood) ■ diabetes ■ gout ■ arthritis ■ under a doctor's care for any serious condition ■ taking any other drug ■ taking any other product that contains aspirin, or any other pain reliever/fever reducer	
Stop use and ask a doctor if	
■ an allergic reaction occurs. Seek medical help right away. ■ migraine headache pain is not relieved or gets worse after first dose ■ new or unexpected symptoms occur ■ stomach pain or upset gets worse or lasts ■ ringing in the ears or loss of hearing occurs	
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	
■ adults 18 years and older: ■ take 2 caplets with a full glass of water ■ if symptoms persist or worsen, ask your doctor ■ do not take more than 2 caplets in 24 hours unless directed by a doctor	

- under 18 years of age: ask a doctor
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Other information

- each caplet contains: calcium, (*insert number of milligrams*)
 - store at 20 - 25°C (68 - 77°F)
 - save carton for full directions and warnings
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Inactive ingredients calcium carbonate, carnauba wax, colloidal silicon dioxide, D&C Red #7 Lake, FD&C blue no. 2, FD&C Red #40 Lake, hydropropyl methylcellulose, microcrystalline sodium, propylene glycol, sodium starch glycolate, starch, titanium dioxide, zinc stearate

Questions or comments? 1-800-331-4536 or www.bayeraspirin.com (*include the days of the week and times of the day when a person is available to respond to questions*)

Please note: The font size, spacing, bolding, and formatting in this mockup are not necessarily compliant with §201.66

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/s/

Thomas Laughren
10/18/01 10:46:00 AM
Signed for Russell Katz, M.D.

Linda Katz
10/18/01 04:37:05 PM