

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-317

APPROVED LABELING

Attachment

Drug Facts

Active ingredients (in each caplet)

Buffered aspirin 500 mg

Purpose

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

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

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