

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-802/S002

APPROVED LABELING

APPROVED

OCT 7 1999

CARTON LABEL COPY- MODIFIED SMALL PACKAGE LABELING FORMAT

Principal display panels (PDP)

NEW

Pain Reliever/Pain Reliever Aid

**EXCEDRIN®
MIGRAINE**

Acetaminophen, Aspirin and Caffeine Tablets

Logo # (of Dosage Units) COATED (*Insert Dosage Form)

BACK PANEL

Drug Facts

Active ingredients (in each tablet)

| | | <i>Purposes</i> |
|---------------|--------|------------------------|
| Acetaminophen | 250 mg | Pain reliever |
| Aspirin | 250 mg | Pain reliever |
| Caffeine | 65 mg | Pain reliever aid |

Uses ■ treats migraine

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 acetaminophen and aspirin or other pain relievers/fever reducers.

Acetaminophen and aspirin may cause liver damage and stomach bleeding.

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

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 so severe as to require bed rest
- bleeding problems
- asthma
- ulcers
- liver disease
- kidney disease
- stomach problems such as heartburn, upset stomach, or stomach pain that do not go away or recur

Ask a doctor or pharmacist before use if you are taking a prescription drug for:

▪ anticoagulation (thinning of the blood) ▪ diabetes ▪ gout ▪ arthritis

Stop use and ask a doctor if ▪ an allergic reaction occurs. Seek medical help right away.

▪ your migraine is not relieved or worsens after first dose

▪ new or unexpected symptoms occur ▪ 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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions ▪ do not take more than directed

▪ adults: take 2 tablets with a full glass of water ▪ if symptoms persist or worsen, ask your doctor

▪ under 18 years of age: ask a doctor before use

Other information ▪ store at 20 - 25°C (68 - 77°F)

▪ read all product information before using. Keep this box for important information.

Inactive ingredients benzoic acid, carnauba wax, hydroxypropylcellulose, hydroxypropyl methylcellulose, microcrystalline cellulose, mineral oil, polysorbate 20, povidone, propylene glycol, simethicone emulsion, sorbitan monolaurate, stearic acid, may also contain: FD&C blue no. 1, titanium dioxide

Questions or comments? Call 1-800-468-7746

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