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MIDRIN®

May 1998L

CAUTION: Federal law prohibits dispensing without prescription.

DESCRIPTION: Each red capsule with pink band contains Isometheptene Mucate USP, 65 mg, Dichloralphenazone USP, 100 mg, and Acetaminophen USP, 325 mg.

Isometheptene Mucate is a white crystalline powder having a characteristic aromatic odor and bitter taste. It is an unsaturated aliphatic amine with sympathomimetic properties.

Dichloralphenazone is a white, microcrystalline powder, with slight odor and tastes saline at first, becoming acrid. It is a mild sedative.

Acetaminophen, a non-salicylate, occurs as a white, odorless, crystalline powder, possessing a slightly bitter taste.

Midrin capsules contain FD&C Yellow No. 6 as a color additive.

ACTIONS: Isometheptene Mucate, a sympathomimetic amine, acts by constricting dilated cranial and cerebral arterioles, thus reducing the stimuli that lead to vascular headaches. Dichloralphenazone, a mild sedative, reduces the patient's emotional reaction to the pain of both vascular and tension headaches. Acetaminophen raises the threshold to painful stimuli, thus exerting an analgesic effect against all types of headaches.

INDICATIONS: For relief of tension and vascular headaches.*

* Based on a review of this drug (isometheptene mucate) by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the other indication as "possibly" effective in the treatment of migraine headache. Final classification of the less-than-effective indication requires further investigation.

CONTRAINDICATIONS: Midrin® is contraindicated in glaucoma and/or severe cases of renal disease, hypertension, organic heart disease, hepatic disease and in those patients who are on monoamine-oxidase (MAO) inhibitor therapy.

PRECAUTIONS: Caution should be observed in hypertension, peripheral vascular disease and after recent cardiovascular attacks.

ADVERSE REACTIONS: Transient dizziness and skin rash may appear in hypersensitive patients. This can usually be eliminated by reducing the dose.

DOSAGE and ADMINISTRATION: FOR RELIEF OF MIGRAINE HEADACHE: The usual adult dosage is two capsules at once, followed by one capsule every hour until relieved, up to 5 capsules within a twelve hour period.

FOR RELIEF OF TENSION HEADACHE: The usual adult dosage is one or two capsules every four hours up to 8 capsules a day.

HOW SUPPLIED: Red capsules imprinted with pink band, the letter "C" and 86120. Bottles of 50 capsules, NDC 0086-0120-05. Bottles of 100 capsules, NDC 0086-0120-10. Bottles of 250 capsules, NDC 0086-0120-25. Store at controlled room temperature 15°-30°C (59°-86°F) in a dry place.

The most recent revision of this labeling is May 1998L.

Printed with food grade ink.

Manufactured for
**CARNRICK
LABORATORIES, INC.**
Pharmaceuticals since 1899
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