PHARMACOLOGICAL ACTION

Data available from animal experiments as well as human studies indicate that chlorzoxazone acts primarily at the level of the spinal cord and subcortical areas of the brain where it inhibits multisynaptic reflex arcs involved in producing and maintaining skeletal muscle spasm of varied etiology. The analgesic action of paracetamol supplements that which results secondarily from muscle relaxation. Paracetamol possesses antipyretic action. Diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID) with analgesic with antipyretic properties. It also has some uricosuric effect. Diclofenac inhibits cyclooxygenase activity with a reduction in the tissue production of prostaglandins such as PgF2 and PgE2.

INDICATIONS

PAZOFLOC tablets are indicated for the relief of severe skeletal muscle spasm and pain associated with such medical and orthopaedic problems as: sprains and strains, myalgias, torticollis, tension headaches, traumatic muscle injuries, low back pain, fibrositis, cervical root and disc syndromes.

WARNINGS

PAZOFLOC is not recommended during pregnancy or lactation since safety in pregnant women or nursing mothers has not been established. Dosages in excess of those recommended may cause severe liver damage.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

a) Adverse Reactions

Occasional patients may develop gastrointestinal disturbances. It is possible, in rare instances, that chlorzoxazone may have been associated with gastrointestinal bleeding. Dizziness, nausea, lightheadedness, malaise, or overstimulation may be noted by an occasional patient. Drowsiness cn
occur with the use of PAZOFLOC and may be additive to drowsiness from the concomitant use of alcohol or other central nervous system depressants. Rarely, petechiae or ecchymoses may develop during treatment. Sensitivity reactions resulting in reversible skin rash or blood disorders may occur, but these are rare. Angioneurotic oedema and anaphylactic reactions are extremely rare. Rarely, a patient may note discoloration of the urine resulting from a phenolic metabolite of chlorzoxazone. This finding is of no known clinical significance. Infrequently, cases have been reported in which the administration of chlorzoxazone or chlorzoxazone containing products was suspected of causing liver damage. Several of these were subsequently determined to be due to underlying diseases rather than to chlorzoxazone (ie. Carcinoma of the head of the pancreas, carcinoma with hepatic metastases, cholelithiasis). The remaining cases had a clinical picture consistent with viral hepatitis or a medicine induced hepatitis. In all of the latter cases the medicine was stopped and the patients recovered. It is not possible to state that the hepatitis in these patients was or was not medicine-induced.

b) Precautions

Store in a safe place out of reach of children.

PAZOFLOC tablets should be used with caution in patients with known allergies or with a history of allergic reactions to medicines. If a sensitivity reaction occurs such as urticaria, redness, or itching of the skin, the medicine should be stopped. If any signs or symptoms suggestive of liver dysfunction are observed the medicine should be discontinued. Patient suffering from liver or kidney disease shoulds take this medicine under medical supervision.

Do not use continuously for longer than ten days without consulting your doctor. Consult your doctor if no relief is obtained with the recommended dosage.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately. Specialized treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest poison centre.

SYMPTOMS

Initially nausea, vomiting, diarrhea and upper abdominal pain associated with drawn, pale faces. Central nervous stimulation, dizziness or headache may be noted, followed by marked loss of muscle tone making voluntary movement impossible. The deep tendon reflexes may be decreased or absent. Respiratory depression may occur with rapid, irregular respiration and intercostals and substernal retraction. The blood pressure is lowered. Liver damage which may be fatal may only appear after a few days. The chief biochemical changes noted in the blood are gross elevation of liver enzymes, some elevation of the bilirubin level, prolongation of prothrombin time and possibly either hypoglycaemia or hyperglycaemia. Kidney failure has been described following acute intoxication.
TREATMENT

Gastric lavage or the induction of emesis (ipecac or apomorphine) followed by 50 grams of activated charcoal given orally to decrease absorption is the best available treatment and should be carried out immediately. Treatment is symptomatic and supportive.

IDENTIFICATION

Light Orange coloured Capsule shaped uncoated Tablets.

PRESENTATION

5 X 10 Tablets in a Alu-Alu Pack

STORAGE INSTRUCTIONS

Store below 30°C in the original pack or in containers which prevent access of light and moisture.

KEEP OUT OF REACH OF CHILDREN