PROFESSIONAL INFORMATION

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**SCHEDULING STATUS: S5**

**PROPRIETARY NAME: TENSTON SA TABLETS**

**(AND DOSAGE FORM) (TABLET)**

**COMPOSITION:**

Each tablet contains:

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| Meprobamate | 150 mg |
| Codeine phosphate | 10 mg |
| Paracetamol | 200 mg |
| Caffeine | 30 mg |
| Contains sugar: Lactose | 100 mg |

**LIST OF EXCIPIENTS:** Calcium hydrogen phosphate, maize starch, magnesium stearate, pregelatinized starch, sodium starch glycollate, USA lake blend and purified water.

**PHARMACOLOGICAL CLASSIFICATION:**

A 2.8 Analgesic combinations

**PHARMACOLOGICAL ACTION:**

TENSTON SA TABLETS have analgesic, antipyretic and muscle-relaxing actions.

**INDICATIONS:**

For the symptomatic relief of mild to moderate pain and fever.

**CONTRAINDICATIONS:**

Patients who must remain alert or who are hypersensitive to any of the ingredients, patients who have acute intermittent porphyria or severe kidney or liver dysfunction. Asthma, respiratory depression, head injuries and conditions in which intracranial pressure is raised, heart failure, secondary to chronic

lung disease, a history of cardiac disease, epilepsy and all convulsive states, patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.

**WARNINGS:**

Dosages in excess of those recommended may cause severe liver damage. TENSTON SA TABLETS may cause drowsiness and patients should not drive vehicles or operate machinery where loss of attention could lead to accidents. Do not use for longer than ten days without consulting your doctor.

**DOSAGE AND DIRECTIONS FOR USE:**

Children: 12 years and older: 1 tablet four times daily.

Adults: 1 to 2 tablets four times daily.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

Paracetamol may cause hypersensitivity reactions resulting in skin rash or blood disorders.

Codeine phosphate may cause constipation, nausea, vomiting, dizziness, drowsiness and skin rashes. Caffeine may cause headache, nausea, insomnia, restlessness, excitement and muscle tremor. Caffeine increases gastric secretion and may cause gastric ulceration. It should be taken with care by persons with a history of peptic ulceration or hyperacidity.

Meprobamate may cause drowsiness, nausea, vomiting, diarrhoea, paraesthesia, hypotension, tachycardia, cardiac arrhythmias, weakness and central effects such as headache, excitement, dizziness, ataxia and disturbances of vision. Hypersensitivity reactions such as skin rashes, urticaria and purpura may occur or may be more severe with angioneurotic oedema, bronchospasm or anuria. Erythema multiforme has been reported. Blood disorders have been reported. Symptoms of porphyria may be exacerbated. Meprobamate may lower tolerance to alcohol and other central nervous system depressants. It may induce the hepatic microsomal enzymes involved in drug metabolism.

Consult your doctor if no relief is obtained with the recommended dosage. Patients suffering from liver or kidney disease should take these tablets under medical supervision.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Symptoms of overdosage include the following: nausea, vomiting, restlessness, sensory disturbances, muscle tremor, diuresis, palpitations, stupor, shock, central stimulation with exhilaration, convulsions, drowsiness, respiratory depression, hypotension with circulatory failure, respiratory collapse, cyanosis and coma. Liver damage which may be fatal may only appear after a few days. Kidney failure has been described following acute intoxication. In the event of overdosage, consult a doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest poison control centre.

**IDENTIFICATION:**

Blue tablets, scored on one side.

**PRESENTATION:**

Containers with 20, 100 and 500 tablets.

**STORAGE INSTRUCTIONS:**

Store at or below 25 °C. Protect from light and moisture.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

E/2.8/86

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Adcock Ingram Limited

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**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

15 May 1974