1.3.1.1. PACKAGE INSERT

SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM:

BESEMAX® (TABLET)

COMPOSITION:

Each tablet contains: paracetamol 450 mg and orphenadrine citrate 35 mg

Sugar free.

List of excipients: colloidal silicon dioxide, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, sodium starch glycolate, stearic acid.

PHARMACOLOGICAL CLASSIFICATION:

A 2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:

BESEMAX has analgesic, antipyretic and skeletal muscle relaxant properties.

INDICATIONS:

Generalised pain and the relief of muscle spasm associated with acute painful musculo-skeletal conditions.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Severe liver function impairment.

Prostatic enlargement, achalasia, bladder neck obstruction, glaucoma, myasthenia gravis, peptic ulcer or stenosing and pyloric or duodenal obstruction.

Patients with porphyria.

WARNINGS AND SPECIAL PRECAUTIONS:

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may have no signs or symptoms, the nearest doctor, hospital or poison control centre must be contacted immediately.

Dosages in excess of those recommended may cause severe liver damage.

Patients suffering from liver or kidney disease should take **BESEMAX** under medical supervision.

Caution is recommended in patients on other central nervous system depression-producing medication as well as patients on anticholinergics or medication with anticholinergic properties.

Use with caution in patients with cardiac disease or arrhythmias, especially tachycardia.

Do not use continuously for more than 10 days without consulting your doctor.

INTERACTIONS:

Orphenadrine may increase central nervous system depression if taken concurrently with alcohol or central nervous system depressants. Anticholinergic effects may be intensified if orphenadrine is taken concurrently with anticholinergics or medication with anticholinergic effects.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults: 2 tablets 3 times a day. Do not exceed the recommended dosage.

SIDE EFFECTS:

Paracetamol:

Haematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia and agranulocytosis have been reported. Pancreatitis, skin rashes and other allergic reactions occur occasionally. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions.

Orphenadrine citrate:

Dryness of the mouth with difficulty in swallowing and talking, thirst, reduced bronchial secretions, dilatation of the pupils (mydriasis) with loss of accommodation (cycloplegia) and photophobia,

flushing and dryness of the skin, transient bradycardia followed by tachycardia, with palpitations and arrhyth-mias, and difficulty in micturition as well as reduction in the tone of motility of the gastrointestinal tract leading to constipation. Occasionally vomiting, confusion, giddiness and staggering may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Paracetamol:

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported. Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Liver injury may become manifest on the second day, (or later) initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Cerebral oedema and non-specific myocardial depression have also occurred.

In the event of overdosage consult your doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible.

Prompt treatment is essential. Any patient who has ingested 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon, acetylcysteine should be administered IV as soon as possible, preferably within 8 hours of overdosage.

IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.

Orally: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

Orphenadrine citrate:

Toxic doses cause tachycardia, rapid respiration, hyperpyrexia and central nervous system stimulation marked by restlessness, confusion, excitement, paranoid and psychotic reactions, hallucinations and delirium, and occasionally seizures or convulsions. A rash may appear on the face or upper trunk. In severe intoxication, central stimulation may give way to central nervous system depression, coma, circulatory and respiratory failure, and death.

Treatment is symptomatic and supportive. Institution of haemodialysis or peritoneal dialysis may be of some benefit if the serum concentration exceeds 4 mcg per 4 ml.

IDENTIFICATION:

White, circular, biconvex tablets with a break-bar on one face.

PRESENTATION:

20, 40 and 120 tablets packed in PVC/aluminium foil blister packs.

50 and 100 tablets packed in white polypropylene securitainers with white low-density polyethylene (LDPE) closures.

120 tablets packed in white high-density polyethylene (HDPE) containers with white LDPE closure or white HDPE screw-on closures.

STORAGE INSTRUCTIONS:

Store at or below 25 ˚C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

30/2.8/0099

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

Adcock Ingram Limited

1 New Road

Erand Gardens

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