CLEAN PACKAGE INSERT
KURRA HEADACHE POWDERS

SCHEDULING STATUS

Not Scheduled

PROPRIETARY NAME (AND DOSAGE FORM):

Kurra headache powders

COMPOSITION:

Each wrapped powder contains:

Aspirin	800 mg
Paracetamol	150 mg
Caffeine	50 mg

PHARMACOLOGICAL CLASSIFICATION:

A 2.8. Analgesic Combinations

PHARMACOLOGICAL ACTION:

KURRA HEADACHE POWDERS combine the analgesic and antipyretic action of aspirin and paracetamol together with the anti-inflammatory action of aspirin.

INDICATIONS:

Relief of mild to moderate pain and fever.

CONTRAINDICATIONS:

Hypersensitivity (allergy) to the medicine (paracetamol and aspirin). KURRA HEADACHE POWDERS should not be given to patients suffering from renal disease,

chronic gastritis, peptic ulcers, dyspepsia, haemophilia or on an oral anticoagulant.

WARNINGS:

1. Aspirin has been implicated in Reye's Syndrome, a rare but serious illness in children and teenagers, with chicken pox or influenza. A doctor should be consulted before aspirin is used in such patients.
2. Do not use continuously for more than ten days without consulting your doctor. Excessive and prolonged use of-this medicine may be dangerous.
3. Dosages in excess of those recommended may cause severe liver damage. Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

DOSAGE AND DIRECTIONS FOR USE:

Adults:

One powder with water, six hourly as needed. For best results take the powder·dry on the tongue followed by a glass of water. DO NOT EXCEED FOUR (4) DOSES PER TWENTY-FOUR (24) HOURS.

NOT FOR USE BY CHILDREN.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Special Precautions:

Consult your doctor if no relief is obtained with the recommended dosage.

Paracetamol

Component: Warning:

Dosages in excess of those recommended may cause severe liver damage. Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

Side-effects:

Sensitivity reactions resulting in reversible skin rash or blood disorders may occur.

Aspirin Component:

Dizziness or irritation of the gastric mucosa and resultant dyspepsia, haematemesis and melaena may occur. Some persons especially asthmatics, exhibit notable sensitivity to aspirin which may provoke various hypersensitivity reactions which may include skin eruptions, paroxysmal bronchospasm and dyspnoea.

It should be administered with caution to patients with impaired renal function, dyspepsia, anaemia and when the patient is dehydrated.

Aspirin may enhance the activity of coumarin anticoagulants and oral anti-diabetic preparations and sulphonamides. Aspirin diminishes the effects of anti-gout preparations such as probenecid and sulphinpyrazone.

Barbiturates and other sedatives may mask the respiratory symptoms of aspirin overdosage and have been reported to enhance its toxicity.

Prolonged use of high doses may lead to anaemia, blood dyscrasias, gastro-intestinal haemorrhage, peptic ulceration and renal papillary necrosis.

The use of aspirin during the first and third trimester of pregnancy is not advised, except under the advice and supervision of a medical doctor.

Caffeine Component:

Caffeine side-effects include nausea, vomiting, abdominal pain, headache and insomnia. Caffeine increases gastric secretions and may cause gastric ulceration. It may also cause anxiety, restlessness, vertigo and palpitations.

KNOWN SYMPTOMS OF OVERDOSAGE ANO PARTICULARS OF ITS TREATMENT:

Paracetamol Component:

Symptoms of overdosage include nausea and vomiting.

Liver damage which may be fatal and may only appear after a few days. Kidney damage has been described following acute intoxication.

Aspirin Component:

These include dizziness, tinnitus, sweating, nausea, vomiting, mental confusion, hyperventilation, respiratory alkalosis, metabolic acidosis, ketosis and depression of the central nervous system. In children serious signs of overdosage may develop rapidly.

Caffeine Component:

Overdosage symptoms include restlessness, excitement, muscle tremor, tinnitus, scintillating scotoma, tachycardia and extrasystoles

Treatment:

Treatment is supportive and symptomatic.

Specialised treatment is essential as soon as possible.

The latest information regarding the treatment of overdosage can be obtained from the nearest poison centre.

In the event of overdosage consult a doctor or take die patient to the nearest hospital immediately.

IDENTIFICATION:

Finely milled white powders.

PRESENTATION:

Cartons of 10, 25, 50 and 100 powders.

STORAGE INSTRUCTION:

Store below 25 °C.

Protect from moisture and light.

Keep out of reach of children.

REGISTRATION NUMBER:

B/2.8/961

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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