For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

MEFTAL - SPAS®

(Mefenamic Acid and Dicyclomine Hydrochloride Tablets)

COMPOSITION :

MEFTAL-SPAS Tablets

Each uncoated tablet contains :

Mefenamic Acid BP ..... 250 mg

Dicyclomine Hydrochloride BP ..... 10 mg

MEFTAL-SPAS DS Tablet

Each uncoated tablet contains :

Mefenamic Acid BP ..... 500 mg

Dicyclomine Hydrochloride BP ..... 20 mg

PHARMACOLOGY

PHARAMACODYNAMICS

Mefenamic Acid is a non-steroidal, anti-inflammatory, analgesic and antipyretic agent. It prevents prostaglandin synthesis by inhibiting cyclooxygenase and blocking peripheral prostaglandin receptors. Dicyclomine has a direct antispasmodic action. It also possesses a weak antimuscarinic effect.

PHARMACOKINETICS

After a single oral dose of 250 mg, peak serum levels of mefenamic acid are attained in 2-4 hours. Half-life is about 2 hours. Mefenamic acid is extensively bound to plasma proteins. Following a single dose, 67% of the drug is excreted in the urine either as unchanged drug or as one or two metabolites. 25% of the dose is excreted in the faeces during the first three days. Dicyclomine Hydrochloride is given orally in the dose of 10 -20 mg 3 times daily for treating gastrointestinal and other spasmodic conditions.

INDICATIONS

MEFTAL-SPAS and MEFTAL-SPAS DS tablets are indicated in the treatment of colic conditions, such as spasmodic dysmenorrhoea, intestinal colic, biliary colic and ureteric colic.

DOSAGE AND ADMINISTRATION

One tablet thrice a day, in most patients. The total daily dose of mefenamic acid should not exceed 1500 mg.

CONTRAINDICATIONS

Meftal - Spas is contraindicated in patients with past of history of hypersensitivity to it. It is also contraindicated in patients with active ulceration or chronic inflammation of either the upper or lower GIT. There is a potential for cross-sensitivity with other NSAIDs.

WARNINGS AND PRECAUTIONS

Meftal-Spas should not be given to patients with significantly impaired renal function. Border line elevation of liver function tests may occur in some patients. Not recommended in pregnancy and nursing mothers. Use with caution in patients having glaucoma, prostate hypertophy, hiatus hemia or reflux oesophagitis.

USE IN PREGNANCY

Not recommended during pregnancy.

USE IN ELDERLY

Elderly patients, in general, are probably more susceptible to anticholingergic adverse effects. Hence appropriate dose reduction is advised.

SIDE EFFECTS

The common side effects occurring with mefenamic acid are gastrointestinal disturbances like diarrhoea, nausea, vomiting and abdominal pain. Peptic ulceration and gastrointestinal bleeding have also been reported. Headache, drowsiness, dizziness, nervousness and renal disturbances have been reported. There may be hypersensitivity reactions like skin rashes and urticaria and occasionally allergic glomerulonephritis or asthma may be precipitated. Reported haematological effects include haemolytic anaemia, agranulocytosis, pancytopoenia, thrombocytopenia or thrombocytopenic purpura and bone marrow aplasia. Renal failure, glomerulonephritis and papilla necrosis have been reported. Therapy should be discontinued if diarrhoea or skin rash occur. In susceptible individuals, dicyclomine may cause dry mouth and thirst. On rare occasions fatigue, blurred vision, constipation, anorexia and dysuria have also been reported.

INTERACTIONS

When administered to patients taking oral anticoagulants, the prothrombin time should be frequently monitored.

OVERDOSAGE AND TREATMENT

Mefenamic acid overdosage has been associated with CNS toxicity, especially with convulsions. Coma has also been reported. Gastric lavage and symptomatic therapy is indicated.

PRESENTATION

MEFTAL-SPAS Tablets are available in a blister pack of 10 tablets.

MEFTAL-SPAS DS Tablets are available in a blister pack of 10 tablets.

STORAGE : Store below 30°C, in a dry place. Protect from light.

SHELF LIFE

MEFTAL-SPAS Tablet	-3 Years
MEFTAL-SPAS DS Tablet	-3 Years

MADE IN INDIA BY
BLUE CROSS LABORATORIES PVT LTD.
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INDIA

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