SCHEDULING STATUS S2

PROPRIETARY NAME (AND DOSAGE FORM)

COLOFAC 135 mg TABLETS

COMPOSITION

1 tablet contains mebeverine HCl (veratric acid, 4-[ethyl(p-methoxy-α-methylphenethyl)amino] butyl ester hydrochloride), 135 mg.

PHARMACOLOGICAL CLASSIFICATION

A. 11.2 Gastro-intestinal anti-spasmodics and cholinolytics.

PHARMACOLOGICAL ACTION

Colofac 135 mg is a musculotropic spasmolytic agent with a selective action, especially on smooth muscle spasms of the gastro-intestinal tract.

In vivo studies showed Colofac 135 mg to have spasmolytic properties, especially on the sphincter of Oddi (20-40 times greater than with papaverine), on the cardia and on the ileum. Little or no antispasmodic effect was seen on the uterus and the bronchial muscles.

Gastric emptying time and intestinal propulsion were affected much less than by papaverine. No significant inhibition of normal peristalsis has been observed.

INDICATIONS

Primary irritable colon characterised by persistent diarrhoea, alternating constipation and diarrhoea, abdominal pain and postprandial distension.

Secondary irritable colon due to organic lesions such as regional enteritis, diverticulitis, specific and non-specific inflammatory conditions of the gastro-intestinal tract.

CONTRA-INDICATIONS

Hypersensitivity to any ingredient in the product.

DOSAGE AND DIRECTIONS FOR USE

135 mg mebeverine hydrochloride (1 tablet) 3 times daily, preferably before meals. After a period of a few weeks when the desired effect has been obtained, the dosage may be gradually reduced.

As atropine-like effects are absent, Colofac 135 mg is not contra-indicated in patients with glaucoma or prostatic hypertrophy.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

After the administration of Colofac 135 mg cases of depression, headache, dizziness, diarrhoea and constipation (most probably not attributable to the medicine) were reported.

The safety of Colofac 135 mg in pregnancy has not been established.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

None known.

IDENTIFICATION

White, round sugar-coated tablets.

PRESENTATION

Packs of 10, 20, 100 and 500 tablets.

STORAGE INSTRUCTIONS

Store in a dry, dark place, at temperatures not exceeding 30°C. Keep out of reach of children.

REGISTRATION NUMBER

Q/11.2/165

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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