1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

PHENERINE (sugar-coated tablet)

COMPOSITION

Each sugar-coated tablet of PHENERINE contains 50 mg of orphenadrine hydrochloride.

Excipients:

Acacia powder, benzoic acid, cetyl palmitate, colloidal silicone dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, propyl hydroxybenzoate sodium, quinoline yellow (C.I. 47005), sodium benzoate, sodium ethyl parabenzoate, sodium methyl parahydroxybenzoate, starch maize, stearic acid, sucrose, talc purified, white colour dye Lennon (C.I. 77891)

Preservatives:

Benzoic acid	0,005 % *m/m*
Propyl hydroxybenzoate sodium	0,00012 % *m/m*
Sodium benzoate	0,00002 % *m/m*
Sodium ethylparabenzoate	0,00004 % *m/m*
Sodium methyl parahydroxybenzoate	0,00006 % *m/m*

Contains sugar: Sucrose 50,42 mg, lactose monohydrate 20 mg

CATEGORY AND CLASS

A 5.4.1 Anti-Parkinsonism preparations.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Orphenadrine hydrochloride is a centrally acting anticholinergic agent of benefit in Parkinsonism. It favourably influences akinesia, rigidity and tremor as well as secondary symptoms such as depressed mood, sialorrhea and hyperhidrosis.

INDICATIONS

Parkinsonism.

CONTRAINDICATIONS

Prostatic enlargement, paralytic ileus, pyloric stenosis, closed-angle glaucoma and patients with a narrow angle between the iris and the cornea. Should be used with caution in conditions characterised by tachycardia, such as thyrotoxicosis, cardiac insufficiency or failure, and in cardiac surgery.

WARNINGS AND SPECIAL PRECAUTIONS

In the treatment of Parkinsonism, increases in dosage, and transfer to other forms of treatment should be gradual and anticholinergic medicines should not be withdrawn abruptly. If higher doses provoke severe mental disturbances, the medicine should be discontinued, but minor reactions may be controlled by reducing the dosage until tolerance has developed.

Excipients

PHENERINE contains lactose monohydrate and sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase insufficiency or fructose intolerance should not take PHENERINE.

INTERACTIONS

The effects of anticholinergic medicines may be enhanced by the concomitant administration of other medicines with anticholinergic properties, such as amantadine, some antihistaminics, butyrophenones and phenothiazines, and tricyclic anti-depressants.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

One tablet twice a day to two tablets four times a day.

SIDE EFFECTS

Dryness of the mouth with difficulty in swallowing, thirst, dilatation of the pupils with loss of accommodation and photophobia, increased intra-ocular pressure, flushing and dryness of the skin, bradycardia followed by tachycardia, with palpitations and arrhythmias, a desire to urinate with the inability to do so, as well as reduction in the tone and motility of the gastointestinal tract leading to constipation.

Occasionally vomiting, giddiness and staggering may occur. Retrosternal pain may occur due to increased gastric reflux.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Tachycardia, rapid or stertorous respiration, hyperpyrexia, restlessness, confusion and excitement, and hallucinations passing into delirium.

Depression of the central nervous system, with hypertension or circulatory failure and respiratory depression.

Treatment

Treatment of acute poisoning is to empty the stomach. A saline purgative should be given to promote peristalsis. Excitement may be controlled by small doses of a short-acting barbiturate. Supportive therapy may require oxygen and assisted respiration, icebags or alcohol sponges for hyperpyrexia, especially in children, bladder catheterisation, and the administration of fluids.

IDENTIFICATION

A light yellow normal biconvex sugar-coated tablet.

PRESENTATION

100 tablets are packed in a white polypropylene container sealed with a white low-density polyethylene cap with vertical ridges on the side and a tamper evident seal, together with a white foam insert or rayon. The container is packed into an outer cardboard carton together with a leaflet.

28, 56 and 84 tablets are packed into pre-printed metallised polyester, laminated with opaque low-density polyethylene, patient ready packs and sealed with a low-density polyethylene ziploc and packed into polyethylene bags.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

L/5.4.1/234

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

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