1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

ESPIRIDE (capsule)

ESPIRIDE ELIXIR

COMPOSITION

Each capsule of ESPIRIDE contains sulpiride 50 mg.

Excipients:

Colloidal silicon dioxide, gelatin, lactose monohydrate, magnesium stearate, purified talc, starch maize, titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 112 mg

Each 5 ml of ESPIRIDE ELIXIR contains sulpiride 25 mg.

Excipients:

Alcohol, disodium edetate, dye Lennon yellow (C.I. 47005), flavour lemon essence No.1, glycerol, saccharin sodium, sodium cyclamate, sorbitol (70 %) solution, methyl hydroxybenzoate, propyl hydroxybenzoate, purified water

Preservatives:

Methyl hydroxybenzoate 0,08 % *m/v*

Propyl hydroxybenzoate 0,02 % *m/v*

Contains alcohol: 5,0 % *v/v*

Contains sugar: Sorbitol 26,058 mg

Contains sweetener: Sodium cyclamate 55 mg, saccharin sodium 2,5 mg

CATERGORY AND CLASS

A 2.6.5 Tranquillisers: Miscellaneous structures

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Sulpiride is a substituted benzamide used chiefly in the management of schizophrenia. It exerts antipsychotic action, anti-emetic actions and an effect on gastrin secretion.

Pharmacokinetic properties

It is absorbed with oral administration and the plasma half-life is about 7 to 9 hours.

INDICATIONS

Reactive depression, depression associated with psychoses of other origins. Prophylaxis and treatment of depressive psychoses.

Schizophrenia, particularly with the symptoms of hallucination, autism, aggressiveness and with withdrawn-inhibited types of schizophrenia. Acute delirium, acute hallucinatory and confused states. Behaviour disorders in all age groups where abnormal aggressive symptoms are in the forefront.

ESPIRIDE is a useful adjunct in the medical treatment of duodenal ulceration of psychosomatic origin.

For the treatment of vertigo. It also has an anti-emetic action.

CONTRAINDICATIONS

Sensitivity to sulpiride or phenothiazines.

ESPIRIDE should not be administered to patients with phaeochromocytoma, with bone-marrow depression and only with caution to patients with hypertension.

Contraindicated in hypomanic patients, in the manic or pre-manic phase of manic-depressive psychosis and in patients with acute mania as it may exacerbate symptoms.

ESPIRIDE is considered to be unsafe in patients with acute porphyria.

The safety in pregnancy has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

Slow decrease in dosages before total withdrawal.

ESPIRIDE should be used with caution in patients with cardiovascular or respiratory disease, or other conditions in which a sudden drop in blood pressure would be undesirable. If it is used in conjunction with other medicine, likely to cause postural hypotension, an adjustment of dosage may be necessary. It should be used with caution in patients with existing tachycardia or cardiac insufficiency and in patients with liver dysfunction or a history of jaundice. It should be used with care in patients with Parkinsonism (see INTERACTIONS). Patients receiving long term therapy should have regular examinations for abnormal pigmentation or ocular changes.

Care is required in patients receiving anticonvulsant therapy (see INTERACTIONS).

ESPIRIDE should be used with care in elderly and debilitated patients.

Effects on ability to drive and use machines

ESPIRIDE may lead to drowsiness and impaired concentration which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients should not operate hazardous machinery or drive motor vehicles or perform potentially hazardous tasks where loss of concentration may lead to accidents.

Excipients

ESPIRIDE capsules contains lactose monohydrate 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 or fructose intolerance should not take ESPIRIDE.

Patients with the rare hereditary condition of sorbitol intolerance should not take ESPIRIDE ELIXIR.

INTERACTIONS

The anti-Parkinsonian actions of agents such as levodopa may be diminished by concurrent administration of ESPIRIDE (see WARNINGS AND SPECIAL PRECAUTIONS).

The bioavailability of ESPIRIDE is reduced when given together with sucralfate or an antacid containing aluminium and magnesium hydroxides. It is recommended that if used concurrently that ESPIRIDE be given before rather than with or after sucralfate or antacids.

ESPIRIDE may enhance the anticholinergic properties of atropine and tricyclic anti-depressants.

ESPIRIDE should not be given in conjunction with other medicine that might cause leucopenia such as phenylbutazone and the thiouracil derivatives. The anti-emetic actions of ESPIRIDE may mask the symptoms of disorders such as gastrointestinal obstruction. The antihypertensive action of adrenergic neuron blocking medicines, such as guanethidine, is reduced by ESPIRIDE.

ESPIRIDE enhances the activity of central nervous system depressants including alcohol, anaesthetics, hypnotics and narcotic analgesics and doses of these agents may need to be reduced.

The anticonvulsant properties of diazepam, phenobarbitone, phenytoin, or other anticonvulsants, are not enhanced by ESPIRIDE, but ESPIRIDE may conversely, lower the convulsive threshold (see WARNINGS AND SPECIAL PRECAUTIONS).

HUMAN REPRODUCTION

The safety in pregnancy has not been established.

DOSAGE AND DIRECTIONS FOR USE

For the treatment of schizophrenia:

Adults: Initial dose of 200 mg to 400 mg twice daily, increasing if necessary to a maximum of 1,2 g twice daily.

Maintenance dose 600 mg to 800 mg per day in divided doses for as long as necessary.

Common, milder psychiatric conditions of shorter duration and behavioural disorders:

Adults: 100 mg to 200 mg daily up to 300 mg per day, in divided doses. For maintenance treatment, reduce or increase as necessary.

Children (6 to 12 years): 3 to 5 mg/kg body mass per day in divided doses.

For gastro-enterology:

Adults: 150 mg to 300 mg daily in divided doses. Maintenance and duration of treatment according to patient's requirements.

For the treatment of vertigo:

Adults: 150 mg to 300 mg daily in divided doses depending upon the intensity of the vertigo.

Slowly decrease the dosage before totally withdrawing ESPIRIDE.

ESPIRIDE should be given in reduced doses to elderly patients.

SIDE EFFECTS

The side effects of ESPIRIDE are mild sedation and extrapyramidal disorders which include acute dystonia, a Parkinsonism-like syndrome, akathisia and the neuroleptic malignant syndrome; tardive dyskinesia and perioral tremor may subsequently develop. Sleep disturbances, overstimulation and agitation may occur. Hypertension, fatigue, impotence, amenorrhoea, galactorrhoea, gynaecomastia and mass gain have been reported. Minor abnormalities in liver function tests may occur.

Other adverse effects of ESPIRIDE therapy may include minimal antimuscarinic effects such as

dry mouth, constipation, urinary retention and mydriasis, as well as insomnia, depression, convulsions, nasal congestion, tachycardia, cardiac arrhythmias, electrocardiographic changes, postural hypotension, miosis, blurred vision, and inhibition of ejaculation.

Allergic reactions include urticaria, exfoliative dermatitis, erythema multiforme and contact sensitivity. Jaundice has occurred and is probably allergic in origin. Prolonged therapy may lead to deposition of pigment in the skin, or more frequently the eyes; corneal and lens opacities have been observed. Photosensitivity reactions also occur.

Various haematological disorders, including haemolytic anaemia, aplastic anaemia, thrombocytopenic purpura and a potentially fatal agranulocytosis have occurred in patients receiving ESPIRIDE. Most cases of agranulocytosis have occurred within 4 to 10 weeks of starting treatment and symptoms such as sore throat or fever should be watched for and white cell counts instituted should they appear.

ESPIRIDE alters endocrine and metabolic functions. Patients have experienced hyperglycaemia and altered glucose tolerance and increased serum-cholesterol concentrations. Body temperature regulation is impaired and may result in both hypo- or hyperthermia depending on environment.

Following the abrupt discontinuation of large doses, withdrawal symptoms may include nausea, vomiting, gastritis and tremors.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

See SIDE EFFECTS.

Treatment

In severe overdosage the stomach should be emptied by aspiration and lavage. Emetics should not be used.

Treatment is symptomatic and supportive.

IDENTIFICATION

ESPIRIDE:

A white powder encapsulated within a No. 3 off-white, opaque capsule, printed with a mortar and pestle and “Lennon” in blue ink.

ESPIRIDE ELIXIR:

A clear, bright, yellowish-green solution.

PRESENTATION

ESPIRIDE:

100 capsules are packed in a white cylindrical polypropylene securitainer with a white low density polyethylene cap with a tamper evident seal.

100 capsules are packed in a white hostalen polypropylene securitainer with a white low density polyethylene cap with a tamper evident seal.

100 capsules are packed in a white linear low density polyethylene securitainer with a white low density polyethylene cap with a tamper evident seal.

28 or 56 capsules are packed in a low density polyethylene Ziploc metallised lay-flat bags. The lay-flat bags are then grouped and packed into polyethylene bags.

ESPIRIDE ELIXIR:

100 ml is packed in an amber round polyvinyl chloride bottle together with a black urea formalin screw on cap with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton.

100 ml is packed in an amber round glass bottle together with a black urea formalin screw on cap with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton.

100 ml is packed in a clear high density polyethylene round bottle with a white low density polyethylene snap on cap. The bottle is placed in an outer cardboard carton.

100 ml is packed in a clear round polyvinylchloride bottle together with a white low density polyethylene snap on cap. The bottle is placed in an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed

STORAGE INSTRUCTIONS

Store at or below 25 °C and protect from light and moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

ESPIRIDE: Y/2.5/386

ESPIRIDE ELIXIR: W/2.5/36

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF

REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration:

ESPIRIDE: 01 November 1993

ESPIRIDE ELIXIR: 17 December 1990

Date of the most recent amendment to the professional information as approved by the Authority: 14 April 1998

Namibia:	NS3
Capsule	04/2.5/0065

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