1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

PASRIN-10 (tablet)

COMPOSITION

Each tablet of PASRIN-10 contains 10 mg of buspirone hydrochloride.

Excipients:

Lactose monohydrate, magnesium stearate, microcrystalline cellulose, starch maize, talc purified

Contains sugar: Lactose monohydrate 144 mg

CATEGORY AND CLASS

A 2.6.5 Tranquilisers, miscellaneous structures

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Buspirone hydrochloride is an anxiolytic medicine. The exact mechanism of buspirone's anxiolytic action in humans is not fully understood. Buspirone does not act through a benzodiazepine-receptor mechanism. Buspirone has been shown to have a high affinity for serotonin (5 - HT_{1A}) receptors in the dorsal raphe neurons and a moderate affinity for brain D_2 -

dopamine receptors.

Pharmacokinetic properties

Buspirone hydrochloride is rapidly absorbed from the gastrointestinal tract reaching peak plasma concentrations 60 to 90 minutes after administration. Systemic bioavailability is low due to extensive first-pass metabolism, but may be further increased by concurrent administration of food. Buspirone is about 95 % bound to plasma proteins. Buspirone clearance is reduced in the presence of renal and hepatic function impairments. The elimination half-life of buspirone has varied between 2 and 11 hours.

INDICATIONS

PASRIN-10 is indicated for the management of anxiety disorders with or without accompanying depression.

CONTRAINDICATIONS

PASRIN-10 is contraindicated in:

- Patients with known hypersensitivity to buspirone hydrochloride.
- Pregnancy and lactation.
- Patients with severe renal or hepatic impairment.
- Patients with a history of seizure disorders.
- Safety and efficacy of PASRIN-10 in children under 18 years have not been established.

WARNINGS AND SPECIAL PRECAUTIONS

PASRIN-10 may lower convulsion threshold.

PASRIN-10 should be used with caution in patients with moderate hepatic or renal impairment,

adjust dosage accordingly. PASRIN-10 has a low incidence of sedation. However, its Central Nervous System (CNS) effects in individual patients may not be predictable.

Concomitant use of alcohol must be avoided.

Effects on ability to drive and use machines

Patients operating machinery or a motor vehicle should do so with caution until the effect the medicine has on them is known.

Excipients

PASRIN-10 contains lactose 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 PASRIN-10.

INTERACTIONS

PASRIN-10 should not be used concomitantly with a monoamine oxidase inhibitor.

Reports have described the occurrence of elevated blood pressure in patients receiving both buspirone and monoamine oxidase inhibitors.

Interactions between PASRIN-10 and benzodiazepines, haloperidol, and chlordiazepoxide have been reported. PASRIN-10 does not exhibit cross-tolerance with benzodiazepines and other sedative/hypnotic medicines. Therefore it will not block possible withdrawal symptoms seen with

cessation of therapy with these medicines.

Patients, who have been using benzodiazepines and other sedative/hypnotic medicines chronically, must be withdrawn gradually from treatment, prior to treatment with PASRIN-10.

HUMAN REPRODUCTION

The use of PASRIN-10 during pregnancy and lactation is contraindicated.

DOSAGE AND DIRECTIONS FOR USE

It is usually given in initial doses of 5 mg two or three times per day in the short term management of anxiety disorders. The dose may be increased in increments of 5 mg at 2 to 3 day intervals if required. The usual effective daily dose is 20 mg to 30 mg daily up to a maximum recommended daily dose of 60 mg in divided doses. In view of PASRIN-10's low propensity to sedate and induce muscle relaxation, patients may not immediately notice the effect of the medication. Clinical experience has also indicated that 1 to 2 weeks treatment may be required before the full anxiolytic action is evident. Safety and effectiveness of PASRIN-10 for prolonged use have not been established.

SIDE EFFECTS

Reported side effects include dizziness, nausea, headache, nervousness, light-headedness, excitement, paraesthesia, sleep disturbances, chest pain, tinnitus and nasal congestion. Hypersensitivity reactions including skin rash and, pruritus may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Nausea, vomiting, dizziness, CNS depression, drowsiness, meiosis and gastric distress are the

most commonly observed symptoms of overdose.

Treatment

General symptomatic and supportive measures should be administered along with immediate gastric lavage. There is no known antidote to PASRIN-10 and it is not dialysable.

IDENTIFICATION

A round, white, flat, bevelled edged, bisected tablet, imprinted with “B1” on one side, and plain on the other side.

PRESENTATION

60 tablets are packed into a white, polypropylene securitainer with a white, low density polyethylene cap, together with a white foam insert or rayon and a leaflet.

60 tablets are packed into a white, high density polyethylene bottle, sealed with an aluminium induction seal and a white, polypropylene cap, together with a white foam insert or rayon. The bottle is then packed into a cardboard container together with a leaflet.

60 tablets are packed in clear polyvinylchloride blister strips sealed with an aluminium foil backing. There are 10 tablets per blister strip and 6 blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

30/2.6.5/0168

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

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Woodmead 2191

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