SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

PURATA 10 (tablet)

PURATA - 15 (tablet)

PURATA-30 (tablet)

COMPOSITION

PURATA 10:

Each tablet of PURATA 10 contains 10 mg of oxazepam.

Excipients:

Lactose monohydrate, magnesium stearate, maize starch

Contains sugar: Lactose monohydrate 100 mg

PURATA - 15:

Each tablet of PURATA - 15 contains 15 mg of oxazepam.

Excipients:

Dye Lennon lake red (C.I. 45430), dye Lennon lake yellow (C.I. 47005), lactose monohydrate, magnesium stearate, maize starch

Contains sugar: Lactose monohydrate 95 mg

PURATA-30:

Each tablet of PURATA-30 contains 30 mg of oxazepam.

Excipients:

Dye Lennon lake red (C.I. 45430), lactose monohydrate, magnesium stearate, maize starch

Contains sugar: Lactose monohydrate 85 mg

CATEGORY AND CLASS

A 2.6 Tranquillisers

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Oxazepam is a benzodiazepine derivative with sedative properties. It is a N-demethylated 3-hydroxylated metabolic product of diazepam. Some muscle relaxation occurs after administration in high dosage. Oxazepam reaches peak plasma concentration in 4 hours and is excreted in the urine as the glucuronide conjugate.

Pharmacokinetic properties

Oxazepam is absorbed from the gastrointestinal tract. Up to 80 % of a dose is excreted in the urine over 72 hours. About 10 % of a dose or less has been recovered from the faeces as free oxazepam.

INDICATIONS

PURATA is used in the treatment of anxiety and tension and to relieve the acute symptoms of the alcohol withdrawal syndrome. PURATA is only indicated when the disorder is severe, disabling or subjecting the individual to extreme stress.

CONTRAINDICATIONS

PURATA should not be given to psychotic patients and in those suffering from mental depression or suicidal tendencies. Caution should be observed when giving PURATA to elderly or debilitated patients who are especially sensitive to its side effects, to patients with

renal or hepatic dysfunction and to patients with closed-angle glaucoma.

PURATA is contraindicated in infants and in patients with known hypersensitivity to PURATA and other benzodiazepines. Pre-existing CNS depression or coma is normally a contraindication.

Use of PURATA in the first trimester of pregnancy has been associated with various congenital malformations in the infant and in the last trimester it has been associated with drowsiness, respiratory depression and intoxication in the newborn infant. For these reasons PURATA is contraindicated in pregnancy (see HUMAN REPRODUCTION).

PURATA is excreted in breast milk and is contraindicated in nursing mothers because of the side effects it can cause in the breastfed infant such as drowsiness, slow heartbeat and breathing problems (see HUMAN REPRODUCTION).

Use with care in porphyria, as safety has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

This medicine may lead to drowsiness or impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant medicines.

Special Precautions

Hypotension has occurred and PURATA should be administered with caution to patients in whom a drop in blood pressure might lead to cardiac complications.

PURATA should be administered with particular care to the following patients:

- The elderly and debilitated - who are at particular risk of oversedation, respiratory

depression and ataxia. (The initial oral dosage should be reduced in these patients);

- patients with pulmonary disease and limited pulmonary reserve (asthma, emphysema, bronchitis);
- patients suffering from impairment of renal or hepatic function, or from hypoalbuminaemia;
- patients suffering from anxiety accompanied by an underlying depressive disorder;
- patients receiving barbiturates or other central nervous system depressants concomitantly with the benzodiazepines. There is an additive risk of central nervous system depression when these medicines are taken together;
- patients should be cautioned regarding the additive effect of alcohol when taken together with the benzodiazepines;
- alcohol abuse and drug abuse (or a history thereof);
- difficulty in swallowing in children;
- patients with myasthenia gravis on account of the pre-existing muscle weakness;
- patients with organic brain changes, particularly arteriosclerosis.

Given during labour the benzodiazepines cross the placenta and may cause floppy-infant syndrome characterised by central respiratory depression, hypothermia and poor sucking (see HUMAN REPRODUCTION).

Epileptic patients, in whom the initiation or abrupt withdrawal of benzodiazepine therapy has occasionally provoked seizures, should exercise particular caution while taking this medicine or other benzodiazepines.

With prolonged treatment, periodic blood counts and liver function tests may be advisable.

PURATA is not recommended for the primary treatment of psychotic illness. PURATA

should not be used alone to treat depression or anxiety with depression (suicide may be precipitated in such patients). PURATA should be used with extreme caution in patients with a history of alcohol or drug abuse.

Dependence

There is a potential for abuse and the development of physical and psychic dependence, especially with prolonged use and high doses. The risk of dependence is also greater in patients with a history of alcohol or drug abuse. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. These may consist of headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability.

In severe cases the following symptoms may occur

Derealisation, depersonalisation, hyperacusis, numbness and tingling of extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.

Rebound effects

A transient syndrome whereby the symptoms that led to treatment with PURATA recur in an enhanced form may occur on withdrawal of treatment. It may be accompanied by other reactions including mood changes, anxiety and restlessness. Since the risk of withdrawal phenomena/rebound phenomena is greater after abrupt discontinuation of treatment it is recommended that the dosage is decreased gradually.

Duration of treatment

The duration of treatment should be as short as possible (see DOSAGE AND DIRECTIONS FOR USE), but should not exceed eight to twelve weeks in case of anxiety, including tapering off process. Extension beyond these periods should not take place without re-

evaluation of the situation. It may be useful to inform the patient when treatment is started that it will be of limited duration and to explain precisely how the dosage will be progressively decreased. However, it is important that the patient should be aware of the possibility of rebound phenomena, thereby minimising anxiety over such symptoms, should they occur while the product is being discontinued.

Effects on ability to drive and use machines

PURATA can lead to a decrease in alertness which can influence the patient's ability to perform tasks such as driving of a motor and the operating of machinery.

Patients should not drive or operate machinery where loss of attention might be hazardous.

Excipients

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 PURATA.

INTERACTIONS

The effects of PURATA may be enhanced by alcohol, barbiturates, phenothiazines, monoamine oxidase inhibitors or tricyclic antidepressants, antihistamines, medicines for colds, muscle relaxants, etc.

HUMAN REPRODUCTION

Use of PURATA in the first trimester of pregnancy has been associated with various congenital malformations in the infant and in the last trimester it has been associated with drowsiness, respiratory depression and intoxication in the newborn infant. For these reasons PURATA is contraindicated in pregnancy (see CONTRAINDICATIONS).

Given during labour the benzodiazepines cross the placenta and may cause floppy-infant syndrome characterised by central respiratory depression, hypothermia and poor sucking (see WARNINGS AND SPECIAL PRECAUTIONS).

PURATA is excreted in breast milk and is contraindicated in nursing mothers because of the side effects it can cause in the breastfed infant such as drowsiness, slow heartbeat and breathing problems (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Treatment should be started with the lowest recommended dose

The maximum dose should not be exceeded.

Treatment of anxiety or for control of symptoms of alcohol withdrawal

Usual dose is 15 mg to 30 mg three or four times per day.

For elderly or debilitated patients

10 mg three times per day.

Treatment should be as short as possible. The patient should be reassessed regularly and the need for continued treatment should be evaluated, especially in case the patient is symptom free. The overall duration of treatment generally should not be more than 8 to

12 weeks, including a tapering off process. In certain cases, extension beyond the maximum treatment period may be necessary; if so, it should not take place without re-evaluation of the patient's status.

SIDE EFFECTS

The adverse effects most commonly encountered are drowsiness and oversedation. Drowsiness is more common in elderly and debilitated patients and in patients receiving high doses. Less commonly, the benzodiazepines may produce depression of mood, disorientation or confusion, lethargy and ataxia.

Other side effects frequently encountered are dizziness, slurred speech, vertigo, light-headedness, confusion, mental depression, fatigue, apathy, constipation and irritability. Less frequently depression, gastrointestinal disturbances such as diarrhoea and indigestion, changes in libido, tremor, blurred vision, urinary retention and incontinence, changes in salivation, jaundice and occasional blood disorders have been reported. The benzodiazepines can cause amnesia. Respiratory depression and hypotension may occasionally occur with high dosage. Large doses may produce syncope.

Paradoxical reactions such as acute hyperexcitable states with rage and hostility have been recorded. If these occur, the medicine should be discontinued.

Tolerance and physical dependence can occur.

Skin rashes, headaches, nausea and frequency of urination have been reported.

The benzodiazepines have a moderate potential for abuse.

Withdrawal symptoms (including convulsions) have occurred following abrupt cessation, especially in patients receiving large doses or prolonged periods.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Sedation, ataxia, dysarthria, hypotension, confusion, respiratory and cardiovascular depression and occasionally sleep and coma have been observed in patients ingesting massive doses with suicidal intent. A few deaths have been reported at doses greater than 700 mg.

Treatment

The stomach should be emptied by aspiration and lavage. There is no specific treatment and recovery usually follows symptomatic and supportive therapy, with particular attention being paid to the maintenance of cardiovascular, respiratory, and renal functions, and to the maintenance of electrolyte balance.

IDENTIFICATION

PURATA 10:

White round, flat, bevelled edged tablet engraved “01” on the one side and plain on the other.

PURATA - 15:

A yellow, round, flat bevelled edged tablet, bisected on one side and plain on the other side.

PURATA-30:

Pink, round, flat, bevelled edged tablet, bisected on one side and plain on the other side.

PRESENTATION

PURATA 10:

100 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton.

250 or 500 tablets are packed in a white polypropylene container and sealed with a white low-density polyethylene cap with a tamper evident seal, together with a white foam insert or rayon**.** The container is packed into an outer cardboard carton.

PURATA - 15:

100 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton.

250 or 500 tablets are packed in a white polypropylene container and sealed with a white low-density polyethylene cap with a tamper evident seal, together with a white foam insert or rayon. The container is packed into an outer cardboard carton.

PURATA-30:

100 or 500 tablets are packed in a white polypropylene container and sealed with a white low-density polyethylene cap with a tamper evident seal, together with a white foam insert or rayon. The container is packed into an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

PURATA 10: K/2.6/323

PURATA - 15: K/2.6/324

PURATA-30: K/2.6/325

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

Dates of registration:

PURATA 10: 29 June 1978

PURATA - 15: 29 June 1978

PURATA-30: 29 June 1978

Date of the most recent amendment to the professional information as approved by the Authority: 10 September 1997

Botswana:	S1C
10 mg	B9322690
15 mg	B9322695
30 mg	B9322700

Namibia:	NS3
10 mg	90/2.6/001141
15 mg	90/2.6/001142
30 mg	90/2.6/001143

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