1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

VALOID (tablet)

VALOID AS (suppository)

VALOID CHILDREN'S SUPPOSITORIES

VALOID PAEDIATRIC SYRUP

COMPOSITION

VALOID:

Each tablet contains cyclizine hydrochloride 50 mg.

Excipients:

Acacia powder, lactose monohydrate, magnesium stearate, maize starch

Contains sugar: Lactose monohydrate 60 mg

VALOID AS:

Each suppository contains cyclizine hydrochloride 100 mg.

Excipients:

Witepsol W35

VALOID CHILDREN'S SUPPOSITORIES:

Each suppository contains cyclizine hydrochloride 50 mg.

Excipients:

Witepsol W35

VALOID PAEDIATRIC SYRUP:

Each 5 ml contains cyclizine hydrochloride 12,5 mg.

Excipients:

Absolute alcohol, glycerol, levomenthol, methyl hydroxybenzoate, purified water, quinolone yellow (C.I. 47005), sodium benzoate, sucrose, sunset yellow (C.I.15985)

Preservatives:

Sodium benzoate	0,1 % *m/v*
Methyl hydroxybenzoate	0,1 % *m/v*

Contains alcohol:

Absolute alcohol	5,76 % *v/v*

Contains sugar: Sucrose 3,4 g, glycerol 630 mg

CATEGORY AND CLASS

A 5.7.2 Anti-emetics and antivertigo preparations

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Cyclizine is a histamine H_1 receptor antagonist of the piperazine class and is useful in the treatment of vertigo. It possesses anticholinergic and anti-emetic properties. The exact mechanism by which cyclizine can prevent or suppress both nausea and vomiting from various causes is unknown. Cyclizine increases lower oesophageal sphincter tone and reduces the sensitivity of the labyrinthine apparatus. It may inhibit the part of the midbrain

known collectively as the emetic centre. The N-demethylated derivative, norcyclizine, has been identified as a metabolite of cyclizine. Norcyclizine has little antihistaminic (H_1) activity compared to cyclizine and has a plasma elimination half-life of approximately 20 hours.

INDICATIONS

VALOID is indicated for the prevention and treatment of nausea and vomiting, including motion sickness, nausea and vomiting caused by narcotic analgesics and vomiting associated with radiotherapy and cancer chemotherapy.

VALOID may be of value in relieving vomiting and attacks of vertigo associated with Ménière's disease and other labyrinthine disorders.

NOTE: VALOID Suppositories are indicated for the relief of nausea and vomiting when oral therapy is inappropriate. Maximal mean plasma concentration of cyclizine are reached approximately 12 hours after administration in volunteers, and where a rapid response is required, a parenteral anti-emetic may be preferable.

CONTRAINDICATIONS

VALOID is contraindicated in individuals who have previously reacted adversely to cyclizine. The safety of VALOID during pregnancy and lactation has not been established.

Antihistamines are contraindicated during acute attacks of asthma due to the anticholinergic effects of this class of medicines.

Anticholinergics should not be used in conditions such as narrow angle glaucoma, urinary retention, prostatic hypertrophy, emphysema, chronic pulmonary disease, shortness of breath, and difficulty in breathing, unless directed by a doctor.

VALOID CHILDREN'S SUPPOSITORIES are not for use in children under 6 years of age.

WARNINGS AND SPECIAL PRECAUTIONS

Paradoxical central nervous system stimulation may occur especially in children with insomnia, nervousness, tachycardia, tremors and convulsions.

Following oral administration, case reports have been documented of fixed drug eruption, generalised chorea, and hypersensitivity hepatitis.

Antihistamines may precipitate epileptiform seizures in patients with focal lesions of the cerebral cortex. Elderly patients may be more susceptible to the central nervous system effects and hypotensive effects of cyclizine. Antihistamines may suppress positive skin test results. There have been no specific studies of VALOID in patients with hepatic and/or renal dysfunction. Cholestatic jaundice has been reported.
Antihistamines may mask the warning signs of damage caused by ototoxic medicines such as aminoglycoside antibiotics.

Effects on ability to drive and use machines

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

Excipients

Sucrose warning:

VALOID PAEDIATRIC SYRUP contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take VALOID PAEDIATRIC SYRUP.

Lactose warning:

VALOID tablet 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 VALOID tablets.

INTERACTIONS

Medicine interactions:

- Patients are warned that VALOID may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.
- The side effects of anticholinergic drugs such as atropine and tricyclic antidepressants may be enhanced by the concomitant administration of antihistamines.
- Monoamine oxidase inhibitors may enhance the antimuscarinic effects of antihistamines. VALOID enhances the soporific effect of pethidine.

HUMAN REPRODUCTION

The safety of VALOID during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Motion sickness:

To prevent motion sickness VALOID should be taken one to two hours before departure and may be repeated three times daily if necessary.

TABLETS:

Not recommended for children under the age of 6 years.

Adults and children over 12 years: 1 tablet (50 mg), may be repeated up to three times daily, not to exceed 200 mg daily.

Children 6 to 12 years: ½ tablet (25 mg), may be repeated up to three times daily, not to exceed 75 mg daily.

SUPPOSITORIES:

THE SUPPOSITORIES MUST BE REMOVED FROM THE PLASTIC SHELL BEFORE USE.

Adults and children over 12 years: Use one adult suppository (100 mg) three times a day as necessary.

Children aged 6 to 12 years: Use one paediatric suppository (50 mg) three times a day as necessary.

NOTE: VALOID CHILDREN'S SUPPOSITORIES MUST NOT be administered to children less than 6 years of age.

PAEDIATRIC SYRUP:

Children 6 to 12 years: 2 medicine measures (10 ml) (25 mg) may be repeated up to three times daily.

Children 2 to 5 years: 1 medicine measure (5 ml) (12,5 mg) may be repeated up to three times daily.

The elderly: There have been no specific studies of VALOID in the elderly.

SIDE EFFECTS

Antimuscarinic effects of antihistamines are dryness of mouth, nose and throat, blurred vision, difficulty in micturition, dysuria and tightness of the chest.

Other side effects of antihistamines include drowsiness, restlessness, lassitude, dizziness, incoordination, gastrointestinal disturbances such as diarrhoea, constipation, nausea and vomiting, epigastric pain, anorexia or increased appetite. Central effects of antihistamines include headache, tinnitus, euphoria, muscular weakness and hypotension.

Hallucinations have been reported, particularly when the dosage recommendations have been exceeded.

Agranulocytosis has been reported.

Other blood disorders including haemolytic anaemia and leucopenia may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Overdosage may be fatal especially in infants and children in whom the main symptoms are central nervous system stimulation and antimuscarinic effects including ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, facial flushing and hyperpyrexia.

Deepening coma, cardiorespiratory collapse and death may occur within 18 hours. In adults the usual symptoms are drowsiness, coma and convulsions.
Hypotension may also occur.

Treatment

Treatment is symptomatic and supportive. In the management of acute overdosage with

VALOID, gastric lavage and supportive measures for respiration and circulation should be performed if necessary. Convulsions should be controlled in the usual way with parenteral anticonvulsant therapy.

IDENTIFICATION

VALOID

White, round, biconvex, scored tablet, marked T4A on one side and plain on the other side.

VALOID AS

A 33,99 mm to 34,0 mm long smooth waxy off-white suppository.

VALOID CHILDREN'S SUPPOSITORIES

A 26,99 mm to 27,0 mm long smooth waxy off-white suppository.

VALOID PAEDIATRIC SYRUP

A clear yellow liquid with a characteristic odour.

PRESENTATION

VALOID

10 or 20 tablets are packed in a clear polyvinylchloride film-coated with polyvinylidene chloride and sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

200 tablets are packed in an amber glass bottle with a white, low density polyethylene screwcap together with a white non-absorbant, non-bleached cotton wool. The bottle is packed into an outer cardboard carton together with a leaflet.

VALOID AS

6 suppositories packed in an opaque white plastic mould with polyvinylchloride laminated

polyethylene, printed with “VALOID 100 mg” in red ink and the batch number and expiry date. One strip of six suppositories is packed into an outer cardboard carton together with a leaflet.

VALOID CHILDREN’S SUPPOSITORIES

6 suppositories packed in an opaque white plastic mould with polyvinylchloride laminated polyethylene, printed with “VALOID 50 mg” in red ink and the batch number and expiry date. One strip of six suppositories is packed into an outer cardboard carton together with a leaflet.

VALOID PAEDIATRIC SYRUP

50 ml are packed into a round, amber glass bottle and sealed with either a plain white aluminium roll-on cap, internally lacquered with an expanded polyethylene liner or a white, high density polyethylene child-resistant tamper evident outer cap with a natural, polypropylene inner cap and a natural, low-density polyethylene tamper evident band together with a uniform expanded polyethylene liner. The bottle is placed in an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

VALOID

Store at or below 25 °C.

Keep in the original container until required for use.

KEEP OUT OF REACH OF CHILDREN.

VALOID AS and VALOID CHILDREN’S SUPPOSITORIES

Store at or below 25 °C in a well-closed container.

Keep in the original container until required for use.

KEEP OUT OF REACH OF CHILDREN.

VALOID PAEDIATRIC SYRUP

Store at or below 25 °C in a well-closed container. Protect from light.

Keep in the original container until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

VALOID:	C/5.7.2/978
VALOID AS:	C/5.7.2/975
VALOID CHILDREN'S SUPPOSITORIES:	C/5.7.2/977
VALOID PAEDIATRIC SYRUP:	D/5.7/97

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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2191

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

Dates of registration:

VALOID:	29 September 1994
VALOID AS:	17 April 1996
VALOID CHILDREN'S SUPPOSITORIES:	05 June 1996
VALOID PAEDIATRIC SYRUP:	01 March 1972

Date of the most recent amendment to the professional information as approved by the authority: 05 June 1996

Botswana:	S3
VALOID AS:	BOT1703074
VALOID CHILDREN'S SUPPOSITORIES:	BOT1703073
VALOID PAEDIATRIC SYRUP:	BOT1703072

Namibia:	NS1
VALOID:	11/5.7.2/0069
VALOID AS:	11/5.7.2/0071
VALOID CHILDREN'S SUPPOSITORIES:	11/5.7.2/0068
VALOID PAEDIATRIC SYRUP:	11/5.7.2/0070

Zimbabwe:	P.
VALOID:	2018/16.2/5697
VALOID AS:	83/16.2/1674
VALOID CHILDREN'S SUPPOSITORIES:	83/16.2/1664
VALOID PAEDIATRIC SYRUP:	80/16.2/1334