PACKAGE INSERT

Biral® sugar-coated tablets

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM:
Biral® sugar-coated tablets.

COMPOSITION:
Each tablet contains:

Valerianae extractum siccum	100,0 mg
Passiflorae extractum siccum	45,0 mg
Contains sugar: Sucrose	133,62 mg
and	
Lactose Monohydrate	32,25 mg

Excipients: colloidal anhydrous silica; microcrystalline cellulose; croscarmellose sodium; povidone (K29 - 32); magnesium stearate; drinking water. [Coating: Talc; calcium carbonate E170; titanium dioxide E171; acacia; hypromellose; white beeswax; carnauba wax; simethicone emulsion; iron oxide red E172; iron oxide yellow E172; iron oxide black E172]

PHARMACOLOGICAL CLASSIFICATION:
A 2.6 Tranquillizers.

PHARMACOLOGICAL ACTION:
Valerian and Passiflora are natural products of plant origin, which act on the central nervous system to bring about a mild sedative action.

INDICATIONS:
Anxiety, restlessness and minor neuroses characterised by the absence of depression.

CONTRAINDICATIONS:
Hypersensitivity to the ingredients.
There are no known contraindications.

INTERACTIONS:
No known interactions.

PREGNANCY AND LACTATION:
Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:
Adults: Unless otherwise directed, initially two tablets should be taken with water three times daily after meals. After improvement or in less severe cases, one tablet should be taken three times daily after meals.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Adverse reactions with normal therapeutic doses are unknown. Should any adverse reaction occur, discontinue medication immediately.
Hypersensitivity has been known to occur with the use of Passiflorae extractum siccum.
Contains lactose/fructose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **Biral®.**
Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucra-seisomaltase insufficiency should not take **Biral®.**
Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Overdose or prolonged use should not give rise to any toxic effects. However, should any severe symptoms occur following overdose, consult a medical practitioner or nearest hospital immediately.

IDENTIFICATION:
Pale pink sugar-coated tablets.

PRESENTATION:
Available in blister strips, packed in cartons of 20, 40 and 100 tablets.

STORAGE INSTRUCTIONS:
Store in a cool, dry place. Store at or below 25 ºC.
KEEP OUT OF REACH OF CHILDREN

REFERENCE NUMBER:
B1503 (Act 101/1965).

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
XIXIA PHARMACEUTICALS (PTY) LTD
4 Brewery Street, Isando, Kempton Park, 1600
Republic of South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:
09 December 2008

VOUBILJET

Biral® suikerbedekte tablette

SKEDULERINGSTATUS: S0

EIENDOMSNAAM EN DOSEERVORM:
Biral® suikerbedekte tablette.

SAMESTELLING:
Elke tablet bevat:

Valerianae extractum siccum	100,0 mg
Passiflorae extractum siccum	45,0 mg
Bevat suiker: Sukrose	133,62 mg
en	
Laktose Monohidraat	32,25 mg

Ander bestanddele: kolloïdale anhidriese silika; mikrokristallyne sellulose; croscarmellose natrium; povidon (K29 - 32); magnesiumstearaat; drinkwater. [Bedekking: Talk; kalsiumkarbonaat E170; titaandioksied E171; acacia; hypromellose; wit byewas; karnauba was; simetikoon-emulsie; ysteroksied rooi E172; ysteroksiedgeel E172; ysteroksied swart E172]

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.6 Bedaarmiddels.

FARMAKOLOGIESE WERKING:
Valerian en Passiflora is natuurlike produkte van plantaardige oorsprong wat op die sentrale senuweestelsel inwerk om ’n ligte kalmerende effek te veroorsaak.

INDIKASIES:
Angs, rusteloosheid en ligte neuroses, wat gekenmerk word deur die afwesigheid van neerslagtigheid.

KONTRA-INDIKASIES:
Hipersensitiwiteit vir die bestanddele. Sover bekend is daar geen kontra-indikasies nie.

INTERAKSIES:
Sover bekend is daar geen interaksies nie.

SWANGERSKAP EN LAKTASIE:
Veiligheid gedurende swangerskap en laktasie is nie bewys nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes: Tensy anders voorgeskryf, is die aanvangsdosis twee tablette met water, drie maal per dag na maaltye. Sodra die toestand verbeter, of vir minder ernstige gevalle, kan een tablet drie maal per dag na maaltye geneem word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte met die normale terapeutiese dosering is onbekend. Indien enige ongunstige reaksie wel voorkom, moet die behandeling gestaak word.
Hipersensitiwiteit teenoor Passiflorae extractum siccum is aangemeld.
Bevat laktose/fruktose. Pasiënte met die seldsame oorerflike probleme van galaktose-onverdraagsaamheid, bv. galactosaemia, die Lapp laktase tekort, of glukose-galaktose wanabsorpsie of fruktose-intoleransie moet **Biral®** nie neem nie.
Bevat sukrose. Pasiënte met ‘n seldsame oorerflike probleme soos fruktose intoleransie, glukose-galaktose wanabsorpsie of sukrase isomaltase ontoereikendheid moet nie **Biral®** neem nie.
Bevat laktose en sukrose, wat ‘n effek mag hê op die glisemiese beheer van pasiënte met diabetes mellitus.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Oordosering of langdurige gebruik behoort geen toksiese uitwerking te hê nie. As oordosering egter hewige reaksies veroorsaak, moet ’n geneesheer of die naaste hospitaal onmiddellik geraadpleeg word.

IDENTIFIKASIE:
Ligpienk suikerbedekte tablette.

AANBIEDING:
Beskikbaar in stulpverpakkings, verpak in kartonne van 20, 40 en 100 tablette.

BERGINGSAANWYSINGS:
Bewaar op ’n koel, droë plek. Bewaar by of onder 25 °C.
HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER:
B1503 (Wet 101/1965).

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIE SERTIFIKAAT:
XIXIA PHARMACEUTICALS (PTY) LTD
4 Brewery Street, Isando, Kempton Park, 1600
Republiek van Suid-Afrika

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:
09 Desember 2008