

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 and	133,62 mg
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 °C.

**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

**PATIENT INFORMATION LEAFLET**

**WHAT YOU NEED TO KNOW ABOUT Biral®**

- Please read this leaflet carefully before you start using this medicine.
- Keep this leaflet with your medicine as you may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

SCHEDULING STATUS **S0**

Biral® is a schedule 0 medicine which means it can be sold without a prescription.

**PROPRIETARY NAME AND DOSAGE FORM**

Biral® sugar-coated tablets.

**WHAT Biral® CONTAINS**

Each Biral® sugar-coated tablet contains:	
Valerianae extractum siccum	100,0 mg
Passiflorae extractum siccum	45,0 mg
Contains sugar: Sucrose and	133,62 mg
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]

**WHAT Biral® IS USED FOR**

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

**BEFORE TAKING Biral®**

Do not take this medicine if you are allergic to the ingredients.

**If you are taking other medicines on a regular basis, the use of this medicine as well may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.**

**If you are pregnant or breastfeeding a baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.**

**HOW TO TAKE Biral®**

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 reactions occur discontinue medication immediately. Hypersensitivity has been known to occur with dry extract of Passion Flower (Passiflora).

Not all side effects reported for this medicine are included in this leaflet. If your general state of health worsens while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Biral® contains lactose/fructose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take Biral®.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Biral®.

Biral® contains lactose and sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

**STORAGE AND DISPOSAL INSTRUCTIONS**

Store in a cool, dry place. Store at or below 25 °C.

**KEEP OUT OF REACH OF CHILDREN.**

Take unused or expired medicine to your doctor, pharmacist or other healthcare professional for safe disposal.

**PRESENTATION**

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

**IDENTIFICATION**

Pale pink sugar-coated tablets.

**REFERENCE NUMBER**

B1503 (Act 101/1965).

**NAME AND ADDRESS OF REGISTRATION HOLDER**

**XIXIA PHARMACEUTICALS (PTY) LTD**  
4 Brewery Street, Isando, Kempton Park, 1600  
Republic of South Africa

**DATE OF PUBLICATION**

09 December 2008



**VOUBILJET****Biral®** suikerbedekte tablette**SKEDULERINGSSTATUS:** **SO****EIENDOMSNAAM EN DOSEERVORM:****Biral®** suikerbedekte tablette.**SAMESTELLING:**

Elke tablet bevat:

Valeriana 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.

**PASIËNT INLIGTINGSTUK****WAT U VAN Biral® BEHOORT TE WEE**

- Lees asseblief die inligtingstuk sorgvuldig deur voordat u die medisyne begin gebruik.
- Hou hierdie inligtingstuk. Dit mag nodig wees om dit later weer te lees.
- As u steeds onseker is, vra asseblief u dokter of apteker.

**SKEDULERINGSSTATUS** **SO**

**Biral®** is geskeduleer as O. Dit beteken dat dit sonder 'n voorskrif verkoop kan word.

**EIENDOMSNAAM EN DOSEERVORM****Biral®** suikerbedekte tablette.**WAT Biral® BEVAT**Elke **Biral®** suikerbedekte tablet bevat:

Valeriana 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]

**WAARVOOR Biral® GEBRUIK WORD**

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

**VOORDAT Biral® GENEEM WORD**

Moenie die medisyne gebruik indien u allergies is vir die bestanddele.

**Indien u ander medisyne op 'n gereelde basis gebruik, kan die bykomende gebruik van die medikasie ongewenste interaksies tot gevolg hê. Raadpleeg asseblief u dokter, apteker of gesondheidswerker vir advies. Indien u swanger is of borsvoed, raadpleeg asseblief u dokter, apteker of gesondheidswerker vir advies voordat u die medikasie begin gebruik.**

**DOSES 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 VOORSORGMATREËLS:**

Neuwe-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 oorerflikke 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 oorerflikke 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 eger hewige reaksies veroorsaak, moet 'n geneesheer of die naaste hospitaal onmiddellik geraadpleeg word.

**IDENTIFIKASIE:**

Ligpienk suikerbedekte tablette.

**AANBIEDING:**

Besikbaar in stulpverpakings, verpak in kartonne van 20, 40 en 100 tablette.

**BERGINGS- EN BESONDERHEDE:**

Bewaar op 'n koel, droë plek. Bewaar by of onder 25 °C.

**HOU BUITE BEREIK VAN KINDERS.****VERWYSINGSNUMMER:**

B1503 (Wet 101/1965).

**NAAM EN BESIGHEIDSAFSAK 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

**HOE OM Biral® TE NEEM**

*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 VOORSORGMATREËLS**

Neuwe-effekte met die normale terapeutiese dosering is onbekend. Indien ongunstige reaksies wel voorkom, moet die behandeling gestaak word. Hipersensitiwiteit teenoor Passiflora ekstrak is aangemeld.

Nie al die newe-effekte wat vir die medisyne gerapporteer is, is in die inligtingstuk gelys nie. Indien u algemene gesondheid verswak terwyl u hierdie medisyne neem, kontak asseblief u dokter, apteker of ander gesondheidswerker vir advies.

**Biral®** bevat laktose/fruktose. Pasiënte met seldsame oorerflikke probleme van laktose/fruktose-, of galaktose intoleransie, moet nie **Biral®** neem nie.

Indien u dokter vir u gesê het dat u 'n intoleransie het vir sommige suikers, kontak u dokter voordat u **Biral®** neem nie.

**Biral®** bevat laktose en sukrose, wat 'n effek mag hê op die beheer van u bloedsuiker indien u diabetes mellitus het.

**BERGINGS- EN VERNIETIGINGS INSTRUKSIES**

Bewaar op 'n koel, droë plek. Bewaar by of onder 25 °C.

**HOU BUITE BEREIK VAN KINDERS.**

Vir veilige vernietiging, neem enige ongebruikte of vervalde medisyne na u dokter, apteker of gesondheidswerker.

**AANBIEDING**

Besikbaar in stulpverpakings, verpak in kartonne van 20, 40 en 100 tablette.

**IDENTIFIKASIE**

Ligpienk suikerbedekte tablette.

**VERWYSINGSNUMMER**

B1503 (Wet 101/1965).

**NAAM EN ADRES VAN REGISTRASIEHOUER****XIXIA PHARMACEUTICALS (PTY) LTD**

4 Brewery Street, Isando, Kempton Park, 1600  
Republiek van Suid-Afrika

**DATUM VAN PUBLIKASIE**

09 Desember 2008



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