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 Lactose Monohydrate	133,62 mg 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 ºC.
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
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Mylan

www.mylansa.co.za

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PASIËNT INLIGTINGSTUK

WAT U VAN Biral® BEHOORT TE WEET

- 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.

SKEDULERINGSTATUS S0

Biral® is geskeduleer as 0. Dit beteken dat dit sonder 'n voorskrif verkoop kan word.

EIENDOMSNAAM EN DOSEERVORM
Biral® suikerbedekte tablette.

WAT Biral® BEVAT
Elke **Biral®** suikerbedekte 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; kroscarmellose natrium; povidon (K29 - 32); magnesiumstearaat; drink-water. [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
Valeriaan 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 ongewensde 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.

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 VOORSORGMAATREËLS
Newe-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 oorerflike 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
Beskikbaar in stulpverpakkings, verpak in kartonne van 20, 40 en 100 tablette.

IDENTIFIKASIE
Ligpienk suikerbedekte tablette.

VERWYSINGSNOMMER
B1503 (Wet 101/1965).

NAAM EN ADRES VAN REGISTRASIEHOUER
XIXIA PHARMACEUTICALS (PTY) LTD
4 Brewery Street, Isando, Kempton Park, 1600
Republiek van Suid-Afrika

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