

SCHEDULING STATUS: **S0**

PATIENT INFORMATION LEAFLET
LOCAL HEALTH HERBAL CALM (Capsules) <i>Valeriana officinalis</i> L. (Valerian), <i>Passiflora incarnata</i> (Passion Flower)
Sugar free

Complementary Medicine: D.33.6 Western Herbal Medicine
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Read all of this insert carefully as it contains important information for you. LOCAL HEALTH HERBAL CALM is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH HERBAL CALM carefully to get the best results from it.

- Keep this leaflet, you may need it again.
- Do not share LOCAL HEALTH HERBAL CALM with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

- What LOCAL HEALTH HERBAL CALM is and what it is used for.
- What you need to know before you take LOCAL HEALTH HERBAL CALM.
- How to take LOCAL HEALTH HERBAL CALM.
- Possible side effects.
- How to store LOCAL HEALTH HERBAL CALM.
- Contents of the pack and other information.

1.What LOCAL HEALTH HERBAL CALM is and what it is used for. LOCAL HEALTH HERBAL CALM is a complementary medicine that:

- Helps to promote sleep as a sleep aid, particularly during times of stress.
- Helps to relieve restlessness and nervousness.

2. What you need to know before you use LOCAL HEALTH HERBAL CALM. Do not take LOCAL HEALTH HERBAL CALM:

- If you are hypersensitive (allergic) to the active ingredients or any of the other ingredients of LOCAL HEALTH HERBAL CALM (listed in section 6).

Warnings and precautions

Take special care:

- If you have a medical condition or if you are currently taking any other medicine.
- To consult a healthcare practitioner should sleeplessness persist for more than 4 weeks (chronic insomnia).
- To consult a healthcare practitioner if symptoms persist or worsen.
- If you are taking other medicines to calm you or make you less anxious (see below **Other medicines and LOCAL HEALTH HERBAL CALM**).
- If you are having any surgical procedure done, you should stop taking LOCAL HEALTH HERBAL CALM two weeks before an operation.

Children and adolescents

Not suitable for individuals 18 years and younger. Consult with your healthcare practitioner before using.

Other medicine and LOCAL HEALTH HERBAL CALM

Always tell your healthcare practitioner if you are taking any other medicine. This includes all complementary or traditional medicines. Not all possible interactions with other medicines may be included in this leaflet. Consult a healthcare practitioner prior to use if you are taking any other medication. The use of alcohol or medication to calm you, make you less anxious or help you sleep (barbiturates and benzodiazepines) together with LOCAL HEALTH HERBAL CALM may make you feel more drowsy or sleepy.

LOCAL HEALTH HERBAL CALM with food and drink
Avoid drinking alcohol if you are taking LOCAL HEALTH HERBAL CALM. See Section 3.

Pregnancy, breastfeeding and fertility

If you are pregnant, planning to become pregnant, or are breastfeeding please consult your doctor, pharmacist or healthcare practitioner before using LOCAL HEALTH HERBAL CALM. Safety in pregnancy has not been established.

Driving and the use of machinery

LOCAL HEALTH HERBAL CALM may make you feel drowsy or sleepy. Do not drive a vehicle or operate any machinery requiring your attention until you know how LOCAL HEALTH HERBAL CALM affects you.

3. How to use LOCAL HEALTH HERBAL CALM.

Do not share your medicines with any other person.

Always give LOCAL HEALTH HERBAL CALM exactly as prescribed in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults 18 years and older

For restlessness/nervousness: Take one capsule up to three times daily, or as directed by your healthcare practitioner.

As a sleep aid: Take one or two capsules an hour before bedtime, or as directed by your healthcare practitioner. Do not exceed the recommended dosage.

4. Possible side effects.

LOCAL HEALTH HERBAL CALM can have side effects. Not all side effects reported for LOCAL HEALTH HERBAL CALM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH HERBAL CALM please consult your healthcare practitioner for advice.

If any of the following happens, stop using LOCAL HEALTH HERBAL CALM and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH HERBAL CALM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- abdominal pain,
- dyspepsia (indigestion),
- bloating,
- diarrhoea,
- rash,
- fatigue,
- headache,
- vertigo.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you are experiencing side effects, inform your doctor or pharmacist. You can also report your side effects to SAHPRA via the **“6.04 Adverse Drug Reaction Form”** found online under SAHPRA’s publications:

http://www.sahpra.org.za/Publications/Index/8. By reporting side-effects you can help provide more information on the safety of LOCAL HEALTH HERBAL CALM.

5. How to store LOCAL HEALTH HERBAL CALM.

- Store at or below 25 °C in a dry place away from moisture and direct sunlight.
- KEEP OUT OF REACH OF CHILDREN.
- Store in the original packaging until required for use.
- Do not use after expiry date on the label.
- Return all unused LOCAL HEALTH HERBAL CALM to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What LOCAL HEALTH HERBAL CALM contains	
Each capsule contains:	
<i>Valeriana officinalis</i> (Valerian)	500 mg
[root, as 50 mg of a 10:1 extract]	
<i>Passiflora incarnata</i> (Passion Flower)	200 mg
[herb, as 50 mg of a 4:1 extract]	

The other ingredients are bovine gelatine, microcrystalline cellulose, and magnesium stearate.

Sugar free

Presentation and identification of LOCAL HEALTH HERBAL CALM

White, size 0, bovine capsules packed into a blister of 10’s in a carton.

Pack size: 20 capsules.

Holder of certificate of Registration
Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685. Careline: 010 589 2729; careline@cjdsa.com; **www.localhealth.co.za**

This pamphlet was last revised in
October 2024

Registration number

Will be allocated by SAHPRA upon registration.

SKEDULERINGSSTATUS: **40**

PASIENTINLIGTINGSBLAD
LOCAL HEALTH HERBAL CALM (Capsules) <i>Valeriana officinalis</i> L. (Valerian), <i>Passiflora incarnata</i> (Passion Flower)
Suikervry.

Komplementêre Medisyne: D.33.6 Westerse Kruie Medisyne
Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy kwaliteit, veiligheid of beoogde gebruik nie.

Lees hierdie inligtingspamflet deeglik deur aangesien dit belangrike inligting vir jou bevat. LOCAL HEALTH HERBAL CALM is beskikbaar sonder 'n dokter se voorskrif om jou gesondheid te handhaaf. Nietemin moet jy LOCAL HEALTH HERBAL CALM steeds versigtig gebruik om die beste resultate te kry.

- Hou hierdie pamflet, jy mag dit weer nodig hê.
- Moet nie LOCAL HEALTH HERBAL CALM met enige ander persoon deel nie.
- Vra jou gesondheidsorgpraktisyn of apteker indien jy meer inligting of advies benodig.

Wat is in hierdie inligtingsblad

- Wat LOCAL HEALTH HERBAL CALM is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy LOCAL HEALTH HERBAL CALM gebruik.
- Hoe om LOCAL HEALTH HERBAL CALM te gebruik.
- Moontlike newe-effekte.
- Hoe om LOCAL HEALTH HERBAL CALM te bêre.
- Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH HERBAL CALM is en waarvoor dit gebruik word. LOCAL HEALTH HERBAL CALM is 'n aanvullende medisyne wat:

- Help om slaap te bevorder as 'n slaaphulpmiddel, veral gedurende tye van stres.
- Help om rusteloosheid en senuweeagtigheid te verlig.

2. Wat jy moet weet voordat jy LOCAL HEALTH HERBAL CALM gebruik.

Moet nie LOCAL HEALTH HERBAL CALM neem nie.

- As jy hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van LOCAL HEALTH HERBAL CALM (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg:

- As jy 'n mediese toestand het of tans ander medisyne gebruik.
- Raadpleeg 'n gesondheidsorgverskaffer as slaaploosheid langer as 4 weke duur (chroniese slapeloosheid).
- Raadpleeg 'n gesondheidsorgverskaffer indien simptome aanhou of vererger.
- As jy ander medisyne gebruik om jou te kalmeer, minder angstig te maak (sien hieronder **Ander medisyne en LOCAL HEALTH HERBAL CALM**).
- As jy enige chirurgiese prosedure ondergaan, moet jy ophou om LOCAL HEALTH HERBAL CALM twee weke voor 'n operasie te gebruik.

Kinders en adolessente

LOCAL HEALTH HERBAL CALM is nie geskik vir individue 18 jaar en jonger nie. Raadpleeg jou gesondheidsorgpraktisyn voordat jy dit gebruik.

Ander medisyne en LOCAL HEALTH HERBAL CALM

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne neem. Dit sluit alle aanvullende of tradisionele medisyne in. Nie alle moontlike interaksies met ander medisyne is in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien jy enige ander medikasie neem. Die gebruik van alkohol of medikasie om jou te kalmeer, minder angstig te maak of te help slaap (barbiturate en bensodiasiepiene) saam met LOCAL HEALTH HERBAL CALM kan veroorsaak dat jy meer lomerig of slaperig voel.

LOCAL HEALTH HERBAL CALM met kos en drinkgoed

Verm y alkoholgebruik as jy LOCAL HEALTH HERBAL CALM neem. Sien Afdeling 3.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is, beplan om swanger te raak, of borsvoed, raadpleeg asseblief jou dokter, apteker of gesondheidsorgpraktisyn voordat jy LOCAL HEALTH HERBAL CALM gebruik. Veiligheid tydens swangerskap is nie vasgestel nie.

Bestuur en gebruik van masjinerie

LOCAL HEALTH HERBAL CALM kan jou lomerig of slaperig laat voel. Moet nie 'n voertuig bestuur of enige masjinerie bedien wat jou aandag vereis totdat jy weet hoe LOCAL HEALTH HERBAL CALM jou beïnvloed nie.

3. Hoe om LOCAL HEALTH HERBAL CALM te gebruik.

Moet nie medisyne wat vir jou voorgeskryf is met ander persone deel nie.

Gebruik altyd LOCAL HEALTH HERBAL CALM presies soos in hierdie pamflet voorgeskryf of soos jou gesondheidsorgpraktisyn jou aangesê het. Raadpleeg jou gesondheidsorgpraktisyn indien jy onseker is.

Vir wassens 18 jaar en ouer

Vir rusteloosheid/senuweeagtigheid: Neem een kapsule tot en met drie maal per dag, of soos aanbeveel deur jou gesondheidsorgverskaffer.

As 'n slaaphulpmiddel: Neem een of twee kapsules een uur voor slaaptyd, of soos aanbeveel deur jou gesondheidsorgverskaffer.

Moet nie die aanbevele dosis oorskry nie.

4. Moontlike newe-effekte.

LOCAL HEALTH HERBAL CALM kan newe-effekte hê.

Nie alle newe-effekte wat vir hierdie medisyne gerapporteer is, is in hierdie pamflet ingesluit nie. As jou algemene gesondheid versleg of jy enige ongewensde effekte ervaar terwyl jy hierdie medisyne gebruik, raadpleeg asseblief jou gesondheidsorgpraktisyn vir advies.

Indien jy enige van die volgende ervaar, hou op om LOCAL HEALTH HERBAL CALM te neem en sê dadelik vir jou dokter of apteker, of gaan na die ongewone afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat sukkel met sluk of asemhaling kan veroorsaak;
- uitslag of jeuk;
- floues.

Dit is baie ernstige newe-effekte. As jy hulle ervaar, kan jy 'n ernstige reaksie op LOCAL HEALTH HERBAL CALM hê. Jy mag dringende mediese aandag of hospitalisasie benodig.

Sê vir jou dokter as jy enige van die volgende opmerk:

- buikpyn,
- dispepsie (indigestie),
- opgeblasenheid,
- diarree,
- uitslag,
- moegheid,
- hoofpyn,
- lighoofdigheid.

As jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van newe-effekte:

As jy enige newe-effekte ervaar, lig asseblief jou dokter of apteker in. Jy kan ook jou newe-effekte aan SAHPRA rapporteer deur die **“6.04 Adverse Drug Reaction Form”** wat aanlyn beskikbaar is onder SAHPRA se publikasies: **http://www.sahpra.org.za/Publications/Index/8.** Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van LOCAL HEALTH HERBAL CALM te verskaf.

5. Berging van LOCAL HEALTH HERBAL CALM.

- Beskerm teen vog en bêre teen of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Moet nie gebruik na die vervaldatum op die etiket nie.
- Stuur alle ongebruikte LOCAL HEALTH HERBAL CALM terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting.

Wat LOCAL HEALTH HERBAL CALM bevat	
Elke kapsule bevat:	
<i>Valeriana officinalis</i> (Valeriaan)	500 mg
[wortel, as 50 mg van n 10:1 ekstrak]	
<i>Passiflora incarnata</i> (Passieblom)	200 mg
[kruie, as 50 mg van n 4:1 ekstrak]	

Ander bestanddele: Beesgelatien kapsule, Mikrokrystallyne Sellulose, Magnesiumstearaat.

Suikervry

Aanbieding en identifikasie van LOCAL HEALTH HERBAL CALM.

Wit, grootte 0, beesgelatien kapsules, verpak in 'n blister van 10’s in 'n karton boksie. Verpakkingsgrootte: 20 kapsules.

Houer van Registrasiesertifikaat:

CJ Distribution, 23 Stagweg, Glen Austin, Johannesburg, Suid-Afrika, 1685. Kliëntediens: 010 589 2729; careline@cjdsa.com; **www.localhealth.co.za**

Hierdie pamflet is laas hersien in

Oktober 2024

Registrasienuommer:

Sal met registrasie deur SAHPRA toegeken word.

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: D.33.6 Western Herbal Medicine

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0

1. NAME OF THE MEDICINE
LOCAL HEALTH HERBAL CALM (Capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:	
<i>Valeriana officinalis</i> (Valerian)	500 mg
[root, as 50 mg of a 10:1 extract]	
<i>Passiflora incarnata</i> (Passion Flower)	200 mg
[herb, as 50 mg of a 4:1 extract]	

Sugar free

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Capsules.

White, size 0, bovine gelatine capsules containing a light brown to brown coloured powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH HERBAL CALM is a complementary medicine that:

- Helps to promote sleep as a sleep aid, particularly during times of stress.
- Helps to relieve restlessness and nervousness.

4.2 Posology and method of administration
Posology

Adults 18 years and older

For restlessness/nervousness: Take one capsule up to three times daily, or as directed by your healthcare practitioner.

As a sleep aid: Take one or two capsules an hour before bedtime, or as directed by your healthcare practitioner.

Do not exceed the recommended dosage.

Method of administration
For oral use.

4.3 Contraindications
Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions to use

Patients should take special care to any of the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions to use
Take special care:

- Patients should take special care with LOCAL HEALTH HERBAL CALM if they are currently taking any medication or if they are suffering from a medical condition.

- Consult a healthcare practitioner should sleeplessness persist for more than 4 weeks (chronic insomnia).
- Consult a healthcare practitioner if symptoms persist or worsen.

- Avoid taking LOCAL HEALTH HERBAL CALM with alcohol or products that cause drowsiness.

- Patients should be advised to discontinue LOCAL HEALTH HERBAL CALM at least 2 weeks before elective surgical procedures. Passion flower and valerian both have central nervous system (CNS) depressant effects and might cause additive CNS depression when combined with anaesthetics and other medications during and after surgical procedures.

4.5 Interactions
Valeriana officinalis (Valerian)

- Alcohol:** valerian can have additive effects when used concomitantly with alcohol.
- CNS depressants:** valerian can have additive sedative effects when used concomitantly with CNS depressant drugs such as barbiturates and benzodiazepines.

4.5 Interactions
Valeriana officinalis (Valerian)

- Alcohol:** valerian can have additive effects when used concomitantly with alcohol.
- CNS depressants:** valerian can have additive sedative effects when used concomitantly with CNS depressant drugs such as barbiturates and benzodiazepines.

4.6 Fertility, pregnancy and lactation
Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

LOCAL HEALTH HERBAL CALM may cause drowsiness, which can affect your ability to drive a vehicle and operate machinery. Patients should take caution before performing activities requiring their attention, until they are reasonably certain that LOCAL HEALTH HERBAL CALM does not adversely affect their performance.

4.8 Undesirable effects

LOCAL HEALTH HERBAL CALM is generally well tolerated.

Valeriana officinalis (Valerian)

Skin and subcutaneous tissue disorders

Frequency unknown: rash.

Gastrointestinal disorders

Frequency unknown: nausea, diarrhoea, vomiting, stomach pain.

Hepatobiliary disorders

Frequency unknown: hepatotoxicity.

Nervous system disorders

Frequency unknown: dizziness, headaches, fatigue, sleepiness, mental dullness.

Psychiatric disorders

Frequency unknown: restlessness, excitability, uneasiness, agitation, vivid dreams.

Passiflora incarnata (Passion Flower)

Musculoskeletal disorders

Frequency unknown: muscle relaxation.

Nervous system disorders

Frequency unknown: sedation, dizziness, ataxia, confusion.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefits/risk balance of the medicine. healthcare practitioners are asked to report any suspected adverse reactions to SAHPRA via the **“6.04 Adverse Drug Reaction Form”**, found online under SAHPRA’s publications: **https://www.sahpra.org.za/Publications/8.**

4.9 Overdose

In the event of an overdose, undesirable effects listed in 4.8 can be precipitated or be of increased severity. Treatment is supportive and symptomatic. Should accidental overdose occur, discontinue use and consult a doctor or pharmacist.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Valeriana officinalis (Valerian)

- Valerian’s anxiolytic, and sedative properties may be due to the effects of its constituents on gamma-aminobutyric acid (GABA), adenosine A1, and serotonin (5-HT) receptors. Valerenic acid and other constituents of valerian are GABA-agonists. Valerian constituents may inhibit the enzyme system responsible for the central catabolism of GABA, increasing GABA concentrations and decreasing CNS activity. Valerian may also bind directly to GABA-A receptors and stimulate the release and reuptake of GABA. In addition to the effects on GABA, valerian might affect sleep regulation via activity on adenosine and serotonin (5-HT1) receptors.

Passiflora incarnata (Passion Flower)

- Data suggest that passion flower inhibits uptake of gamma-aminobutyric acid (GABA) into neuronal synapses, and has affinity for GABA(A) and GABA(B) receptors.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on LOCAL HEALTH HERBAL CALM.

Valeriana officinalis (Valerian)