PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

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CALMETTES coated tablets

Valerian dispert powder

Contains sugar. Each film-coated tablet contains 47,43 mg sucrose and 7,80 mg lactose monohydrate.

Read all of this leaflet carefully because it contains important information for you

CALMETTES is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use CALMETTES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CALMETTES with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms do not improve.

What is in this leaflet

1. What CALMETTES is and what it is used for.
2. What you need to know before you take CALMETTES.
3. How to take CALMETTES .
4. Possible side effects.
5. How to store CALMETTES.
6. Contents of the pack and other information.

1. What CALMETTES is and what it is used for

CALMETTES is used to help you relax if you are nervous or stressed. It is indicated for relief of nervous tension and anxiety.

2. What you need to know before you take CALMETTES

Do not take CALMETTES:

- If you are hypersensitive (allergic) to valerian root or any of the other ingredients in CALMETTES (listed in section 6).

Warnings and precautions

CALMETTES may enhance the effects of alcohol, sedatives (used to make you relax), tranquillisers (used to reduce anxiety or nervous tension) or other medicines used to help you sleep. Ask your doctor before you take CALMETTES with alcohol or these medicines.
Take special care with CALMETTES if you have a history of liver dysfunction or severe liver disease.

Children and adolescents

CALMETTES is not recommended for use in children under 12 years of age.

Other medicines and CALMETTES

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this CALMETTES.
CALMETTES is not recommended during pregnancy and breastfeeding.

Driving and using machines

CALMETTES may cause side-effects which may affect your ability to drive or use machines. Do not drive or operate machines until you know how CALMETTES affects you.

CALMETTES contains sucrose and lactose monohydrate

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

3. How to take CALMETTES

Do not share your medicines with any other person.

Always take CALMETTES exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of CALMETTES is too strong or too weak, tell your doctor or pharmacist.

Adults:

Two or three tablets – The dosage may be repeated up to three times daily if necessary.

Children:

One tablet – The dosage may be repeated up to three times daily if necessary.

To overcome nervous tension and over-excitement at bedtime, children may take two tablets and adults five tablets half an hour before going to bed.

The tablets must be swallowed whole with water or milk.

If you take more CALMETTES than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CALMETTES

Take your CALMETTES as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CALMETTES can have side-effects.

Not all side-effects reported for CALMETTES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CALMETTES, please consult your health care provider for advice.

If any of the following happens, stop taking CALMETTES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, angkles, facte, lips and mouth or throat, which may cause diffuculty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- Dizziness
- Depression.
- Excessive sweating.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting 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 CALMETTES.

5. How to store CALMETTES

- Store at or below 25 °C, in a dry place.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton / blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CALMETTES contains

The active substance is valerian dispert powder (extract of plant root *Valeriana officinalis*).

The other ingredients are anhydrous colloidal silicon dioxide, beeswax, carmellose sodium, carnauba wax, gum arabic, hypromellose, lactose monohydrate, light magnesium oxide, macrogol 4000, macrogol 6000, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone, shellac, sucrose, talcum and titanium dioxide (E171).

What CALMETTES looks like and contents of the pack

White, sugar-coated tablet.

CALMETTES is packed in PVC/PVDC/aluminium blister strips in an outer carton.

CALMETTES is available in packs of 20, 60 or 100 coated tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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This leaflet was last revised in

Date of registration: 25 February 1974

Date of revision: 26 January 2023

Registration number

F/2.6/60

Namibia: 04/2.6/1104