

Proposed professional information for PLEASURE CBD capsules

COMPLEMENTARY MEDICINE:

COMBINATION PRODUCT (WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT)

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

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

PLEASURE CBD capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Eriosema kraussianum (ubangalala) 209 mg

[Dried root powder]

Tribulus terrestris L. 47,5 mg

[Fruits, 13:1 extract standardised to 90 % saponins, providing 617,5 mg dried herb equivalent]

Panax ginseng C.A.Mey. 45 mg

[Stems and leaves, 20:1 extract standardised to 80 % ginsenosides, providing 900 mg dried herb equivalent]

Ginkgo biloba L. 40 mg

[Leaves, 50:1 extract providing 2 g dried herb equivalent]

Schisandra chinensis (Turcz.) Baill. (schisandra berry) 40 mg

[Fruits, 5:1 extract standardised to 2 % schizandrin, providing 2 g dried herb equivalent]

Lepidium meyenii Walp. (maca) 15 mg

[Roots, 50:1 extract, providing 750 mg dried herb equivalent]

Epimedium brevicornu Maxim. (horny goat weed) 10 mg

[Leaves, 150:1 extract standardised to 98 % epimedium, providing 1,5 g dried herb equivalent]

Cannabis sativa L. (CBD isolate) 5 mg

[hemp leaves and flowers, standardised to 99,9 % cannabidiol isolate]

Cyanocobalamin (vitamin B12) 12,5 µg

Sugar free.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules.

Clear hypromellose capsules containing a beige coloured powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

PLEASURE CBD may assist in increasing libido and blood flow, improving arousal and sexual stimulation to enhance the sexual experience in both men and women.

PLEASURE CBD may also assist in promoting sperm motility and count, semen quality and longer lasting erections.

4.2 Posology and method of administration

Take two capsules with water and food one hour before intimate interaction on active days, and one capsule with water and food in the mornings or evenings on non-active days.

Do not exceed the maximum daily dose of four capsules.

4.3 Contraindications

Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.

4.4 Special warnings and precautions for use

Bleeding disorders:

PLEASURE CBD may have antiplatelet effects and may increase the risk of bleeding when used in patients with bleeding disorders. Patients should be advised to discontinue PLEASURE CBD at least 2 weeks prior to surgical procedures (see section 4.5).

Diabetes mellitus:

PLEASURE CBD may increase insulin levels and/or decrease blood glucose levels and cause hypoglycaemia. Dose adjustment of antidiabetic medicine might be necessary (see section 4.5).

Hypotension:

PLEASURE CBD may reduce blood pressure. Caution is advised with patients suffering from low blood pressure and/or patients taking medicines for hypertension (see section 4.5).

Epilepsy:

PLEASURE CBD can cause seizures. Caution is advised for patients with epilepsy and/or taking medicines for epilepsy (see section 4.5).

4.5 Interaction with other medicines and other forms of interaction

CNS depressants:

PLEASURE CBD can have CNS depressant effects which might be enhanced with concomitant use with medicines and herbal supplements with sedative properties.

Anticoagulant/antiplatelet medicines:

PLEASURE CBD may reduce platelet aggregation and may enhance the effects of anticoagulant/antiplatelet medicines including aspirin, clopidogrel, heparin, warfarin, or herbal supplements, such as garlic, ginger and ginkgo. Concomitant use may increase the risk of bleeding and caution is advised (see section 4.4).

Antidiabetic medicines:

Concomitant use of PLEASURE CBD with antidiabetic medicines including glimepiride, metformin, insulin, or herbal supplements such as ginger, ginseng and garlic may have an additive effect with antidiabetic medicine and cause hypoglycaemia (see section 4.4).

Antihypertensive medicines:

PLEASURE CBD may decrease blood pressure. Concomitant use with antihypertensive medicines including captopril, enalapril, losartan, valsartan and amlodipine, or herbal supplements such as coenzyme Q10 and fish oil, may increase the risk of hypotension (see section 4.4).

Anticonvulsant medicines:

Caution is advised for patients taking medicines for epilepsy as PLEASURE CBD can cause seizures (see section 4.4).

Cytochrome P450 substrates:

PLEASURE CBD may increase the levels of medicines that are metabolised by CYP3A4 and increase their effects and adverse effects. Medicines that may be affected include propranolol, losartan, diltiazem, nicardipine, verapamil, ketoconazole and itraconazole.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. PLEASURE CBD should not be taken during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

PLEASURE CBD may cause side effects such as somnolence and can affect the ability to drive a vehicle and use machines (see section 4.8).

Caution is advised before driving a vehicle or operating machinery until the effects of PLEASURE CBD are known.

4.8 Undesirable effects

PLEASURE CBD is generally well tolerated.

Psychiatric disorders:

Frequent: somnolence.

Nervous system disorders:

Frequent: headache.

Gastrointestinal disorders:

Frequent: nausea, vomiting, diarrhoea, gastrointestinal irritation.

Skin and subcutaneous tissue disorders:

Frequent: skin rash.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<http://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class:

D 33.7 Combination Product

PLEASURE CBD is a supplement containing CBD, various herbal components and vitamins, which may assist in enhancing the sexual experience in both men and women.

5.2 Pharmacokinetic properties

Ubangalala root probably delays the rate of absorption of the bioactive compounds from the gastrointestinal tract, and thereby prolongs the duration of action of compounds in the body.

There is insufficient reliable information about the pharmacokinetics of tribulus and maca.

Ginkgolide A, ginkgolide B and bilobalide concentrations are found in the body after administration of ginkgo extracts with half-lives of 4, 6 and 3 hours, respectively. The amounts of each excreted unchanged in the urine were approximately 70 %, 50 % and 30 %, respectively.

After oral administration of ginseng, compound K is absorbed into the blood over 24 hours.

Schizandrine, schizandrol A and gomisin A levels increase in plasma after oral administration of schisandra. Gomisin A is 80 % protein bound. Schizandrol A is detected at one hour after oral administration, and the half-life of gomisin A is approximately 70 minutes.

Horny goat weed constituents, icariin and epimedin C, is absorbed intestinally. Epimedin C has better absorption in the duodenum, while icariin has better absorption in the duodenum and ileum.

Cannabidiol (CBD) from *Cannabis sativa* L. is poorly absorbed after oral administration. CBD and its metabolites have a half-life of about 58 hours and is primarily excreted in the faeces, with minimal renal elimination.

Vitamin B12 is an essential water-soluble vitamin. It is absorbed in the terminal ileum and is mainly stored in the liver. Vitamin D is excreted via urine, faeces and bile.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C in a dry place protected from light.

Keep the container in the outer carton.

Keep the container tightly closed.

6.5 Nature and contents of container

Amber glass container with a black polypropylene cap.

Pack size: 60 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Baltimore (Pty) Ltd

Foregate Square 1A

Heerengracht

Foreshore

Cape Town

8001

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.