

Professional information for CBD DARK CHOCOLATE

COMPLEMENTARY MEDICINE: WESTERN HERBAL MEDICINE

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

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

CBD DARK CHOCOLATE bar.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g bar contains:

Cannabis sativa L. (CBD isolate) 20 mg

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

Contains 40,5 g sugar.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Bar.

A dark brown chocolate bar.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

CBD DARK CHOCOLATE may assist with general health and well-being.

4.2 Posology and method of administration

Take one bar daily.

Do not exceed the maximum daily dose of one bar daily.

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

- CBD DARK CHOCOLATE contains 40,5 g of sugar per bar. This should be taken into account in patients with diabetes mellitus.
- Patients with rare hereditary problems of fructose intolerance or glucose-galactose malabsorption should not take CBD DARK CHOCOLATE.
- CBD DARK CHOCOLATE may worsen the symptoms of Parkinson's disease in some patients. Caution is advised for patients suffering from Parkinson's disease.

4.5 Interaction with other medicines and other forms of interaction

CNS depressants:

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

Cytochrome P450 substrates:

CBD DARK CHOCOLATE 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. CBD DARK CHOCOLATE should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

CBD DARK CHOCOLATE may cause side effects such as drowsiness 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 CBD DARK CHOCOLATE are known.

4.8 Undesirable effects

CBD DARK CHOCOLATE is generally well tolerated.

Psychiatric disorders:

Frequent: drowsiness.

Gastrointestinal disorders:

Frequent: nausea, vomiting, diarrhoea, gastrointestinal irritation.

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 33.6 Western herbal medicine.

CBD DARK CHOCOLATE is a complementary product containing CBD which may assist with general health and well-being.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cocoa butter

Cocoa mass

Natural vanilla

Soybean lecithin (emulsifier)

Sugar.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

A 100 g dark chocolate bar wrapped in black foil and a green wrapper.

Pack size: 1 bar.

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.

10. DATE OF REVISION OF THE TEXT

This leaflet was last revised in October 2020.