

## Professional information for CBD SKIN REPAIR GEL

### 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 SKIN REPAIR GEL

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL contains:

<i>Aloe ferox</i> Mill. (aloe)	40 g
[leaves]	
<i>Cannabis sativa</i> L. (CBD isolate)	0,1 g
[hemp leaves and flowers, standardised to 99,9 % cannabidiol isolate]	
<i>Lavandula angustifolia</i> Mill. (lavender)	0,02 g
[flowering tops]	
<i>Matricaria recutita</i> L. (chamomile)	0,02 g
[flowers]	

For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Gel.

A viscous water-based light-opaque white gel.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

CBD SKIN REPAIR GEL supports healthy skin by hydrating, repairing and restoring the balance of the skin. CBD SKIN REPAIR GEL may also assist in treating dry, irritated, inflamed and infected skin, bites, burns, rashes and stings.

### **4.2 Posology and method of administration**

Apply generously to the areas of concern with enough gel to cover the surface. Repeat as needed.

### **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**

For external use only.

Avoid contact with the eyes and mucous membranes.

Do not apply to broken or damaged skin.

### **4.5 Interaction with other medicines and other forms of interaction**

None known.

### **4.6 Fertility, pregnancy and lactation**

Safety in pregnancy and lactation has not been established. CBD SKIN REPAIR GEL should not be used during pregnancy or lactation.

### **4.7 Effects on ability to drive and use machines**

None known.

#### **4.8 Undesirable effects**

CBD SKIN REPAIR GEL is generally well tolerated.

Skin rash or skin burn may occur. Discontinue use if any allergic skin reactions occur.

#### **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**

Overdose is unlikely. If necessary, remove the gel by washing with warm water. 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 SKIN REPAIR GEL is a complementary product containing CBD, aloe, lavender and chamomile. CBD SKIN REPAIR GEL supports healthy skin by hydrating, repairing and restoring the balance of the skin. CBD SKIN REPAIR GEL may also assist in treating dry, irritated, inflamed and infected skin, bites, burns, rashes and stings.

#### **5.2 Pharmacokinetic properties**

CBD SKIN REPAIR GEL has little to no systemic absorption from the skin.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Acritamer 940 (carbomer)

Euxyl 9010 (phenoxyethanol/ethylhexyl glycerine)

Polysorbate 20

Vegetable glycerine

Water.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

24 months.

### **6.4 Special precautions for storage**

Store at or below 25 °C.

Keep the tube tightly closed.

### **6.5 Nature and contents of container**

A 100 mL white co-extruded tube with white flip cap and silver aluminium seal on the dispensing mouth.

Pack size: 100 mL.

### **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.