

PROFESSIONAL INFORMATION

Category D: human complementary medicine. This medicine has not been evaluated by the SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Obel Hemorrhoid & Fissure Treatment gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients: Glycerin (10%), Witch Hazel Extract (10%), Mineral Oil (0.1%).

3. PHARMACEUTICAL FORM

Obel Hemorrhoid & Fissure Treatment gel is a clear yellow gel.

4. CLINICAL PARTICULARS

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4.1. Therapeutic Indications

Obel Hemorrhoid & Fissure Treatment gel is used for temporary relief of pain, burning and itching associated with hemorrhoids. Helps relieve anorectal discomforts and temporarily reduces hemorrhoidal tissue, making bowel movements less painful.

4.2. Posology and method of administration

Posology

Adults: Apply up to four times daily, especially in the morning, at night, or after each bowel movement.

Method of administration

Clean area before applying gel. Apply externally or in the lower part of the anal canal only.

4.3. Contraindications

Avoid if allergic or sensitive to any of the listed ingredients. Do not exceed recommended dosage(s).

4.4. Special warnings and precautions for use

Obel Hemorrhoid & Fissure Treatment gel must not be used if hypersensitive (allergic) to any ingredients.

4.5. Interaction with other medicines and other forms of interaction

If you are taking prescription medication, consult a healthcare practitioner prior to use. Obel Hemorrhoid & Fissure Treatment gel are not known to react badly with any types medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Obel Hemorrhoid & Fissure Treatment gel should not be used during pregnancy and a healthcare provider should be consulted for advice prior to taking Obel Hemorrhoid & Fissure Treatment gel when breastfeeding.

4.7. Effects on ability to drive and use machines.

No effects on the ability to drive and use machines has been reported.

4.8. Undesirable effects

None known. Should general health worsen, or if any untoward effects are experienced while using this product, please consult a doctor, pharmacist, or other health care professional for advice.

4.9. Overdose

It is difficult to administer too much Obel Hemorrhoid & Fissure Treatment gel due to it being a topical medicine. If anyone, especially a child, accidentally ingests Obel Hemorrhoid & Fissure Treatment Gel contact your doctor or local poison centre immediately. Obel Hemorrhoid & Fissure Treatment Gel should not be used continuously for longer than one week. If symptoms persist consult your doctor. If you see a doctor or have to go to hospital for any reason, tell them what medicines you are taking.

If you forget to take a dose of Obel Hemorrhoid & Fissure Treatment Gel:

Do not take a double dose to make up for forgotten individual doses..

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

33.6 Western Herbal Medicine. Obel Hemorrhoid & Fissure Treatment gel contain substances for temporary relief of pain, burning and itching associated with hemorrhoids. Helps relieve anorectal discomforts and temporarily reduces hemorrhoidal tissue, making bowel movements less painful.

5.2. Pharmacokinetic properties

There is no pharmacokinetic data available on the active ingredients via the route of administration described.

5.3. Preclinical safety data

There is no preclinical safety data available on the active ingredients via the route of administration described.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive ingredients: Sodium Benzoate, Menthol, Allantoin, Clove Oil (*Syzygium aromaticum*), Mineral Oil, Dimethyl Sulfone, Vitamin E (tocopherol acetate), Carbomer, carboxymethyl cellulose, Zinc Oxide, Co-enzyme Q10, Ethoxylated sorbitan monooleate, Disodium edetate, Sodium Benzoate, Potassium Sorbate, Ginko biloba, Green tea (*Camellia sinensis*), Garlic (*Allium sativum*), Horse Chest Nut (*Aesculus hippocastanum*), Devils Claw (*Harpagophytum procumbens*), Cocoa (*Theobroma cacao*), Centella asiatica, Turmeric (*Curcuma longa*).

6.2. Incompatibilities: None

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store below 30 °C in a cool, dry place. Store out of reach of children. Do not use after the expiry date stated on the bottle. The expiry date refers to the last day of the month.

6.5. Nature and contents of container

Obel Hemorrhoid & Fissure Treatment Gel is a clear yellow gel in a white plastic bottle.

Special precautions for disposal

No special requirements.

7. PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION

Galileo Labs Ltd.

5630 Venice Blvd #1119, LA, CA 90019.

3rd Floor, 14505 Bannister Road SE,

Calgary, AB, T2X 3J3.

Name and Address of Holder of Certificate of Registration

Microbel Laboratories (Pty) Ltd,

86 Gazelle Ave, Corporate Park South,

Midrand, Gauteng, 1685, South Africa.

Email: info@microbel.co.za

+27 11 076 4000

8. REGISTRATION NUMBER(S)

Application Number: TBC by SAHPRA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

TBA by SAHPRA. Date of Revision: April 2025