

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S0

**PROPRIETARY NAME (AND DOSAGE FORM):**

Obel Hemorrhoid & Fissure Treatment Gel

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

**Category D: Complementary Medicine**, D33.6 Western herbal medicine

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

**Read this leaflet carefully as it contains important information for you.**

Obel Hemorrhoid & Fissure Treatment Gel are available without a doctor's prescription for Hemorrhoid & Fissure Treatment. Nevertheless, you still need to use Obel Hemorrhoid & Fissure Treatment Gel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Obel Hemorrhoid & Fissure Treatment Gel with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

- You must consult a doctor if your condition worsens or does not improve after 7 days.

**What is in this leaflet:**

- 1. What Obel Hemorrhoid & Fissure Treatment Gel are and what it is used for**
- 2. What you need to know before you use Obel Hemorrhoid & Fissure Treatment Gel**
- 3. How to use Obel Hemorrhoid & Fissure Treatment Gel**
- 4. Possible side effects**
- 5. How to store Obel Hemorrhoid & Fissure Treatment Gel**
- 6. Contents of the pack and other information**

**1. WHAT OBEL HEMORRHOID & FISSURE TREATMENT GEL, ARE AND WHAT THEY ARE USED FOR**

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

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE OBEL HEMORRHOID & FISSURE TREATMENT GEL**

Do not use Obel Hemorrhoid & Fissure Treatment Gel if you are hypersensitive (allergic) to any ingredients.

If you are unsure if you should use Obel Hemorrhoid & Fissure Treatment Gel, talk to your doctor or pharmacist.

**Warnings and precautions:**

For external use only. Do not use if allergic to any ingredients. Stop use and consult a doctor if bleeding, allergic reaction, or no improvement within 7 days occurs.

If you are taking prescription medication, consult a healthcare practitioner prior to use. If any unwanted/adverse effect develops, discontinue use and consult your doctor or pharmacist. Use is described in adults aged 18 years and older.

**Tell your healthcare provide prior to use**

- If you are taking any prescription medication
- If you are pregnant, trying to become pregnant or are breast-feeding ask your doctor or pharmacist for advice

**Pregnancy and Breastfeeding**

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.

### **Driving and using machines**

Obel Hemorrhoid & Fissure Treatment Gel has no known effect on an individual's ability to drive or operate machinery.

Taking other medicines with Obel Hemorrhoid & Fissure Treatment Gel

Always tell your healthcare provider if you are taking any other medicine. Obel Hemorrhoid & Fissure Treatment Gel is not known to react badly with any types or food or drink but may affect absorption of nutrients and medications.

### **3. HOW TO USE OBEL HEMORRHOID & FISSURE TREATMENT GEL**

**The usual dose and method of administration is:**

#### **Adults:**

Clean area before applying gel. Apply externally or in the lower part of the anal canal only. Apply up to four times daily, especially in the morning, at night, or after each bowel movement.

**If you apply more Obel Hemorrhoid & Fissure Treatment Gel than you should:**

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 center 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.

#### **4. POSSIBLE SIDE EFFECTS**

None known. If any side effects are experienced, please tell your doctor or pharmacist.

Obel Hemorrhoid & Fissure Treatment Gel is not known to react badly with any other medicines or any types of food or drink.

Should your general health worsen, or if you experience any untoward effects while using this product, please consult your doctor, pharmacist, or other health care professional for advice. If you notice any side effects not mentioned in this leaflet, please inform 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: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of Obel Hemorrhoid & Fissure Treatment Gel.

## **5. HOW TO STORE OBEL HEMORRHOID & FISSURE TREATMENT GEL**

Store in a cool, dry place (below 30°C). Store out of reach of children. Store out of reach of children. Store in the original package / container. Do not store in a bathroom. Do not use after the expiry date printed on the bottle. The expiry date refers to the last day of that month. Do not use Obel Hemorrhoid & Fissure Treatment Gel if you notice visible signs of deterioration. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets). Shelf life: 2 years

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

What Obel Hemorrhoid & Fissure Treatment Gel contains:

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

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, Ginkgo 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*).

**What Obel Hemorrhoid & Fissure Treatment Gel looks like and contents of the pack:**

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

**Distributed by:**

Galileo Labs Ltd.

5630 Venice Blvd #1119, LA, CA 90019.

3rd Floor, 14505 Bannister Road SE,

Calgary, AB, T2X 3J3.

[customercare@obellabs.co.za](mailto:customercare@obellabs.co.za)

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25 March 2025

**Registration/Application number**

Application Number: TBC

Access to the corresponding Professional Information (PI): [www.obellabs.co.za](http://www.obellabs.co.za)

## PASIËNTINLIGTINGSPAMFLET

**SKEDULERINGSSTATUS:** S0

### **EIENDOMSNAAM (STERKTE EN DOSEERVORM)**

Obel Aambei & Fisuur Behandeling Gel

Aktiewe bestanddele: Gliserien (10%), Hamamelis-uittreksel (10%), Minerale Olie (0.1%).

**Kategorie D: Komplementêre Medisyne.** D 33.6. Westerse kruiegedisyne

Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer ten opsigte van kwaliteit, veiligheid of voorgenome gebruik nie.

**Lees dié hele pamflet aandagtig deur, dit bevat belangrike inligting.**

**OBEL AAMBEI & FISUUR BEHANDELING GEL** is beskikbaar sonder 'n voorskrif van die dokter, vir sypsterverteringsondersteuning. Nietemin, **OBEL AAMBEI & FISUUR BEHANDELING GEL** moet nogtans versigtig gebruik word om die beste resultate te verkry.

- Moenie hierdie pamflet weggooi nie. U mag dit moontlik weer moet lees.
- Moenie **OBEL AAMBEI & FISUUR BEHANDELING GEL** met enige ander person deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- Besoek 'n dokter as u simptome vererger of nie na 7 dae verbeter nie.

## **WAT IS IN HIERDIE PAMFLET**

1. Wat **OBEL AAMBEI & FISUUR BEHANDELING GEL** is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **OBEL AAMBEI & FISUUR BEHANDELING GEL** gebruik.
3. Hoe om **OBEL AAMBEI & FISUUR BEHANDELING GEL** te gebruik.
4. Moontlike newe-effekte.
5. Bergingsaanwysings vir **OBEL AAMBEI & FISUUR BEHANDELING GEL**.
6. Inhoud van die verpakking en ander inligting.

## **1. WAT OBEL AAMBEI & FISUUR BEHANDELING GEL IS EN WAARVOOR DIT GEBRUIK WORD:**

**OBEL AAMBEI & FISUUR BEHANDELING GEL** word gebruik vir tēmpêrere pyn verligting, brand en jeuk geassosieer met aambeie. Dit hulp met anorektaal ongemak en tydelike vermindering van hemorrojale weefsel wat dermbeweging minder pynlik maak.

## **2. WAT U MOET WEET VOORDAT OBEL AAMBEI & FISUUR BEHANDELING GEL**

### **GEBRUIK WORD:**

Moenie **OBEL AAMBEI & FISUUR BEHANDELING GEL** gebruik indien u hipersensitief (allergies) is vir enige bestandele. Indien u onseker is om Obel Aambei & Fissur Behandel Gel te gebruik, konsulteer u gesondheidsorgverskaffer of apteker.

### **WAARSKUWINGS EN VOORSORGMAATREËLS:**

Slegs vir eksterne gebruik. Moet dit nie gebruik as u allergies is vir enige bestanddele nie. Stop gebruik en raadpleeg 'n dokter as bloeding, allergiese reaksie of geen verbetering binne 7 dae voorkom nie.

As u voorskifmedikasie neem, raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. As enige ongewenste / nadelike effek ontwikkel, staak die gebruik en raadpleeg jou dokter of apteker. Gebruik word beskryf in volassenes van 18 jaar en ouer.

### **Vertel jou gesondheidsorg voor gebruik**

- As jy enige voorskifmedikasie neem
- As jy swanger is, probeer om swanger te raak of borsvoed, vra jou dokter of apteker vir raad.

## **Swangerskap en borsvoeding**

Obel Aambei & Fisuur Behandeling Gel moet nie tydens swangerskap gebruik word nie en 'n gesondheidsorgverskaffer moet geraadpeeg word vir advies voordat Obel Aambei & Fisuur Behandeling Gel geneem word tydens borsvoeding.

## **Bestuur en gebruik van masjinerie**

Obel Aambei & Fisuur Behandeling Gel het geen bekende effek op 'n individu se vermoë om te bestuur of masjinerie te bestuur nie.

Neem ander medisyne saam met Obel Aambei & Fisuur Behandeling Gel.

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medikasie neem. Dit is nie bekend dat Obel Aambei & Fisuur Behandeling Gel sleg reageer met enige soorte kos of drank nie, maar kan die opname van voedingstowwe en medikasie beïnvloed.

## **3. HOE OM OBEL AAMBEI & FISUUR BEHANDELING GEL TE GEBRUIK**

**Die gewone dosis en metode van toediening is:**

### **Volwassenes:**

Maak area skoon voordat gel toegedien word. Dien slegs ektern of in die onderste deel van die anale kanaal toe. Dien tot vier keer per dag toe, veral soggens, snags of na elke stoelgang.

### **As jy meer Obel Aambei &Fisuur Behandeling Gel aanwend as jy moet:**

Dit is moeilik of te veel Obel Aambei & Fisuur Behandeling Gel toe te dien omdat dit 'n aktuele medisyne is. As iemand, veral 'n kind per ongeluk Obel Aambei & Fisuur Behandeling Gel inneem, kontak jou dokter of plaaslike gifsentrum onmiddellik. Obel Aambei & Fisuur Behandeling Gel moet nie langer as een week aaneenlopend gebruik word nie. As simptome voortduur, raadpeelg jou dokter. As jy 'n dokter sien of om een of ander rede hopsitaal toe moet gaan, vertel hulle watter medisyne jy neem.

As jy vergeet om 'n dosis Obel Aambei & Fisuur Behandeling Gel te neem:

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

#### **4. MOONTLIKE NEWE-EFFEKTE:**

Niks bekend nie. As enige newe-effekte ervaar word, vertel asseblief jou dokter of apteker.

Dit is nie bekend dat Obel Aambei & Fisuur Behandeling Gel sleg reageer met enige ander medisyne of enige soorte kos of drank nie.

As jou algemene gesondheid vererger, of as jy enige ongewenste effekte ervaar terwyl jy hierdie produk gebruik, raadpleeg asseblief jou dokter, apteker of ander gesondheidswerker vir advies. As jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis. Jy kan ook

newe-effekte aan SAHPRA rapporteer via die 6.04 “Adverse Drug Reaction Reporting Form”, wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.order.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van Obel Aambei & Fisuur Behandeling Gel te verskaf.

## **5. BERGINGSAAWYSINGS VIR OBEL AAMBEI & FISUUR BEHANDELING GEL**

Bewaar in 'n koel, droeë plek, teen of benede 30 °C. Bêre buite bereik van kinders. Berg in die oorspronklike verpakking. Moet nie in 'n badkamer bêre nie. Moet dit nie gebruik na die vervaldatum wat op die bottles gedruk is nie. Die vervaldatum verwys na die laaste dag van daardie maand. Moenie Obel Aambei & Fisuur Behandeling Gel gebruik as jy sigbare tekens van agteruitgang opmerk nie. Stuur alle ongebruikte medisyne terug na jou apteker. Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie. Raklewe: 2 jaar.

## **6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING**

### **WAT OBEL AAMBEI & FISUUR BEHANDELING GEL BEVAT**

Aktiewe bestanddele: Gliserien (10%), Hamamelis-uittreksel (10%), Minerale Olie (0.1%).

Onaktiewe bestanddele: Natriumbenzoaat, Menthol, Allantoïen, Naeltjie-olie (Syzygium aromaticum), Minerale Olie, Dimetielsulfoon, Vitamien E (Tokoferolsaetaat), Karbomeer, karboksimetriellsellulose, sinkoksied, Koensiem Q10, Etoxylated sorbitanmonooleaat, Dinatriumedetaat, Natriumbenzoaat, Kaliumsorbaat, Ginko biloba, groen tee (Camellia sinensis), Knoffel (Allium sativum), Perdeborsmoer (Aesculus Hippocastanum), Duiwelsklou (Harpagophytum procumbens), Kakao (Theobroma cacao), Centella asiatica, Borrie (Cucuma longa).

**Voorkoms van Obel Aambei & Fisuur Behandeling Gel en inhoud van die verpakking:**

Obel Aambei & Fisuur Behandeling Gel is 'n helder geel gel in 'n wit plastiekbottle.

**Versprei deur:**

Galileo Labs Ltd

5630 Venice Blvd #1119, LA, CA 90019.

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**Naam en adres van houer van registrasiesertifikaat**

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**Datum van laaste hersiening**

25 Maart 2025

**Registrasie/Aansoeknommer:**

TBA.

**Toegang tot ooreenstemmende Professionele Inligting (PI):** [www.obellabs.co.za](http://www.obellabs.co.za)