

# Leaflet

## **ULKOX®**

### Hydrogel

#### **Description**

ULKOX® is a medical device presented as hydrogel in an aluminium tube with a separated cannula which contains Fucocert® (polysaccharide) and glycerine as moisturizers, as well as *Olea europaea* leaf extract, included because of its antioxidant properties. The presence of Carbopol 980® provides an isolating and protective barrier for the lesion. The combination of these components, together with the capability to reduce the alkalinity through its slightly acidic pH, gives ULKOX® the ability to modulate the environment of the lesion, thus promoting and speeding up the healing process.

#### **Intended use**

ULKOX® is intended for the healing of anal fissures.

#### **Presentation**

Carton box containing 1 aluminium tube of 15 g or of 30 g with a separated cannula.

#### **Composition**

Each tube contains: 2 mg/g of Fucocert®, 250 mg/g of Glycerine, 13 mg/g of Carbopol 980®, 1 mg/g of *Olea europaea* leaf extract, 20 mg/g of Geogard Ultra®, 1 mg/g of disodium EDTA, 20 mg/g of Trietanolamine and purified water in sufficient quantity.

#### **Instructions for use**

- Wash your hands thoroughly before and after each application
- Before the application of the product clean the affected area with warm water and mild soap and dry.
- Unscrew the tube cap
- For external lesions, apply the amount of gel to the anal region with one finger, using the tip of your finger to overcome the sphincter resistance.
- Should the product be applied inside the rectum, screw the cannula on the tube, lubricate the cannula with a small quantity of product and gently introduce it in the rectum. By putting a slight pressure on the tube, apply a small amount of the product. After its use, unscrew the cannula and carefully clean it for further uses.

#### **Dosage**

ULKOX® is intended to be used in children and adults.

ULKOX® is a multidose product: the content of the same tube can be used for several applications on the same patient.

ULKOX® can be used throughout the whole healing process. It is recommended to make applications after bowel movements and personal grooming; as a rule, apply several times a day.

#### **Warnings and Precautions**

- This medical device is not a pharmacological treatment. It can be administered concomitantly with another treatment prescribed by a healthcare professional, if needed.
- The safety and efficacy of ULKOX® has not yet been established in pregnant women or during breastfeeding period. Therefore, the use of ULKOX® in this patient groups is not recommended unless otherwise advised by a Health Care Professional.
- Do not use the medical device after the expiry date printed on the package.
- Once opened, do not use after 6 months.
- It can be used on lesions with clinical signs of infection, under a physician supervision.

- Each tube must be used for a single patient to avoid cross-contaminations.
- Do not apply the gel (or remove it if it has been applied) in the event of a change in colour or bad odour.
- Do not use the medical device if the tube and/or the cannula are opened or damaged.
- Do not store above 25°C. Do not freeze.
- For topical use only. Not for oral use.
- In case of any reaction in the application area, or any adverse event, stop usage and consult your physician.
- Keep this medical device out of sight and reach of children.
- Any serious incident that has occurred using the medical device should be reported to the manufacturer and the local competent authority.

### **Contraindications**

ULKOX® must not be used in patients with known hypersensitivity to any component listed in the composition of the product.

### **Side effects**

No relevant side effects related to the use of ULKOX® have been reported in clinical studies. A summary of safety and clinical performance is available in the European database on medical devices (Eudamed - <https://ec.europa.eu/tools/eudamed>), where it is linked to the Basic UDI-DI of ULKOX® (843659383ULA823NA).

### **Interactions**






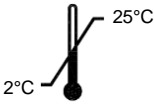



No relevant interactions related to the use of ULKOX® have been reported.



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### Meaning of the symbols used

SYMBOL	TITLE	DESCRIPTION OF SYMBOL
	Manufacturer	Indicates the medical device manufacturer, as defined in Medical Device Regulation 2017/745.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for variety reasons, be presented on the medical device itself.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed, in this special case between 2°C and 25°C.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Medical device	Indicates that the product is a medical device.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.