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	<b>BLEFACALM Kit</b>		
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## 1. NAME OF THE COSMETIC PRODUCT

BlefaCalm® Kit

## 2. INGREDIENT LIST

The ingredients of the components of BlefaCalm® Kit are:

BlefaCalm® Gel: Purified water / Glycerin / Decyl glucoside / Disodium cocoamphodiacetate / Sodium carboxymethylcellulose / Panthenol / Maltodextrin / Caffeine / Sodium chloride / Allantoin / Melaleuca alternifolia leaf oil / Lactic acid.

BlefaCalm® Wipes: Purified water / disodium edta / Glicerol (PEG-6 Caprylic/capric glycerides) / PEG-6 / Panthenol / Betaina / Alantoina / Melaleuca Alternifolia (Tea Tree) Leaf Oil / PEG-40 Hydrogenated castor oil / 2-phenoxyethanol, Chlorphenesin / Trietanolamina

BlefaCalm® Eye Patch: Purified water / Iron powder / Activated carbon / Sodium chloride / Vermiculite extract.

## 3. DOSAGE FORM

BlefaCalm® Kit includes the following products:

- 2 sterile single-dose blister packs containing BlefaCalm® Gel, gel in single-dose container.
- 4 BlefaCalm® Wipes, aqueous solution that impregnates wipes for external application on the eyelid surface.
- 1 BlefaCalm® Eyepatch, textile mask made of non-woven fabric.
- 2 Cleaning swabs.
- 1 Towel.

## 4. PROPERTIES AND USES.

### 4.1 Properties

BlefaCalm® Kit is a kit for professional use to be used by the eye care professional in order to perform a deep cleaning of the external eyelid area.

The Kit contains BlefaCalm® Eye Patch, a self-heating disposable eye mask that provides moist heat to the eyelids and periocular area. When you open the BlefaCalm® Eye Patch and put on the mask with your eyes closed, the product automatically begins to heat up to a temperature of about 40°C and stays warm for about 20 minutes, releasing a fine, moist steam that helps hydrate the eyelid and periocular area. This comfortable warmth helps reduce the feeling of eye strain and promotes the dissolution of solid fats from the eyelids for later elimination.

Subsequently, BlefaCalm® Gel is applied using the cleaning swab. BlefaCalm® Gel is a sterile, preservative-free formulation in gel form contained in a single-dose blister pack. Its non-irritating formula contains tea tree oil, an ingredient that helps reduce the settlement of microorganisms on eyelids and eyelashes, performing an intense cleaning of eyelashes and external eyelid area. In addition, it contains allantoin and dexpanthenol, substances that promote cell regeneration and protection, and provide a pleasant feeling of comfort.

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Finally, BlefeCalm® Wipes is a non-greasy and non-irritating formulation in the form of a sterile aqueous solution impregnated on a wipe that mechanically effectively removes secretions and residues that are deposited at the base of the eyelashes, keeping them in optimal conditions.

#### 4.2 Uses

BlefaCalm® Kit is used for intense cleaning. It is recommended for users where cleaning with other daily hygiene products is insufficient or when the condition of the eyelids, eyelashes and eyelid edge requires a deeper cleaning.

BlefaCalm® Kit is also used to improve the overall state of eye health as it removes eye secretions and debris that settle on the eyelids and eyelashes.

#### 4.3 Dosage and method of administration

BlefaCalm® Kit is a product for professional use.

1. Open the BlefaCalm® Kit and spread the towel included inside on your work surface.
2. Open the BlefaCalm® Eye Patch Heat Mask. Place it with the white side in contact with the eyelids and hold the mask with the elastic bands around the ears. Close your eyes and leave on for 20 minutes, it will warm up once the product is opened.
3. To perform eyelid cleaning, follow these steps:
  - Lay the patient's head horizontally.
  - Insert one of the swabs into the open single-dose blister pack so that it is completely covered by BlefaCalm® Gel.
  - With the swab, apply BlefaCalm® Gel to the lash line, ensuring that it is completely covered by the Gel.
  - Using the swab, gently rub the upper lash line and eyelid margin using a combination of lateral, vertical, and circular motions for 30 to 90 seconds until the gel turns into a lather.
4. Rinse vigorously with sterile isotonic saline.
5. Using BlefaCalm® Non-Woven Wipes, dry and clean the area.
6. After performing upper eyelid cleaning, perform lower eyelid cleaning. After this, repeat in the other eye.

#### 4.4 Contraindications

The products contained in the BlefaCalm® Kit should not be administered to patients with: Known hypersensitivity to any of the components of the formula listed in the composition.

For BlefaCalm® Eye Patch, do not use this product if you have fundal bleeding, glaucoma, or other eye injuries. Do not use this product if you have eczema, or other skin conditions of the periocular area. Do not use this product with contact lenses in place. If the temperature is too high while using it, it is recommended to discontinue use to avoid skin burns.

#### 4.5 Special warnings and precautions for use

- External Use Only: This product is intended for use on the skin, Do not ingest.
- Wash your hands before use.
- Remove contact lenses before use.
- Keep your eyes closed during use. The product is intended for application on eyelids and eyelashes, not to apply to the open eye.

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- Once each of the products is opened, use it immediately.
- Products are for single use only, do not reuse them.
- Do not use the product after the expiry date indicated on the packaging.
- In case of allergy to any of its components, do not use this product.
- Keep in a cool, dry place, out of the reach of light.

#### **4.6 Drug Interaction and Other Forms of Interaction**

They have not been described. BlefaCalm® Kit can be used in conjunction with medications.

#### **4.7 Pregnancy, breastfeeding and children**

No adverse effects have been reported during pregnancy or during breastfeeding.

No adverse effects have been reported during use in children.

#### **4.8 Effects on the ability to drive and use machinery**

They have not been described.

#### **4.9 Adverse reactions**

No side effects have been detected related to the use of BlefaCalm® Kit. If discomfort is detected, discontinue use of the product and consult your doctor or pharmacist.

#### **4.10 Overdosage**

In case of accidental ingestion, consult the National Toxicological Information Service, telephone: 91 562 0420

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties.**

It is not applicable.

#### **5.2 Pharmacokinetic properties.**

It is not applicable.

#### **5.3 Preclinical safety data.**

No relevant safety issues have been identified in relation to the application of Blefacalm® Kit in humans.

### **6. PHARMACEUTICAL DATA.**


#### **6.1 Incompatibilities.**

They have not been described.

#### **6.2 Validity Period.**

BlefaCalm® Gel: 24 meses

BlefaCalm® Eye Patch: 36 meses

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BlefaCalm® Toallitas: 36 meses

This product should not be used with a date after the expiration date.

### **6.3 Special storage precautions**

Keep out of sunlight.

### **6.4 Nature and contents of the container.**

Cardboard case.

### **6.5 Instructions for use/handling.**

External Use Only: This product is intended for use on the skin of the eyelids, Do not ingest. Apply to the eyelids, eyelashes and eyelid edge with eyes closed.

## **7. ADMINISTRATIVE DATA.**

### **7.1 Status.**

Cosmetic Product

### **7.2 UK Distributor:**

Positive Impact (Sales) Ltd  
Swallow House  
Theaklen Drive  
St Leonards-On-Sea  
East Sussex  
TN38 9AZ  
01424 851 375  
sales@positiveimpact.co.uk

### **7.3 Manufacturer.**

Laboratorios Tiedra S.L.  
CL Pintores, 5  
28923 Alcorcón  
Spain  
Tel 91 643 41 40

### **7.4 National Code - PVPIVA recommended.**

PVO 49 €.

## **CHANGE CONTROL**

Revision	Changes Made	Date
0	Preparation of the document	23/10/24