

# navibler<sup>®</sup> TERP

## A FULL RANGE OF EYELID CLEANSING FOAMS



A natural way to help keep your eyelids and eyelashes clean, comfortable and healthy.

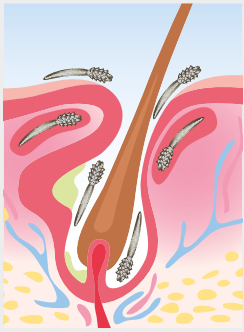
Helps to eliminate secretions and debris from eyelids and eyelashes colonized by bacteria and Demodex.

**NOVAX<sup>®</sup>**  
PHARMA

NAVIBLEF<sup>®</sup> TERP is an innovative range of **foams** designed for daily and intensive care of eyelids and eyelashes. Recommended to remove ocular secretions caused by allergic and inflammatory conditions associated with:

- Demodex,
- Blepharitis and blepharo-conjunctivitis,
- Meibomian gland dysfunction (MGD),
- Rosacea,
- Burning, itchiness or irritation,
- Redness, swelling and other eyelid margin diseases on the face.

## DO YOU KNOW DEMODEX?



**Demodex mites (Demodex folliculorum and Demodex brevis) are the most common ectoparasites infesting the pilosebaceous unit of the skin.**

Uncontrolled Demodex infestation (demodicosis) has been implicated in several diseases of the skin, including rosacea, with papulopustular skin lesions and perifollicular inflammatory infiltrate.

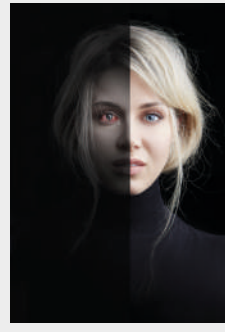
Often, once demodicosis occurs on the face, it can spread and flourish on the eyelids and eyelashes. In case of abundant secretions and residues, a daily use of Naviblef is recommended.

**Demodex (eyelid mites), which is a commonly overlooked cause of ocular inflammation, may be linked to many ocular conditions such as blepharitis.** In the morning, it can result in symptoms including itching and irritation because of the eyelid mites' aversion to light.

At night, Demodex mites are active and come out to mate and lay their eggs onto the lashes. Then, in the morning, mites crawl back into the follicle, causing the patient to itch. The diagnosis of Demodex is very challenging. Not only does it often go unnoticed but it can also be rendered even more difficult in situations where patients with a heavy infestation are asymptomatic despite having "a lot of Demodex".

**In some other instances patients may develop an allergy to the Demodex mites causing severe itching and inflammation, which can interfere with the diagnosis.**

## WHAT IS BLEPHARITIS?



**Blepharitis is a common chronic condition that causes inflammation of the eyelids.** It leads to red rimmed, sore eyes, sometimes with crusting at the roots of the eyelashes, and tearing.

Blepharitis can also lead to the development of tear film problems: abnormal or decreased oil secretions that are part of the tear film can result in excess tearing or dry eye. Because tears are necessary to keep the cornea healthy, tear film problems can make people more at risk for corneal infections.

**Blepharitis can be caused by Demodex (which is an etiologic factor in chronic blepharitis).** In fact, a Demodex infestation is found in 30% of patients with chronic blepharitis. In addition, conjunctival inflammation, meibomian gland dysfunction and concomitant bacterial infections can also lead to the development of Blepharitis symptoms.

**The condition can be difficult to manage because it tends to recur, as such a regular cleansing regime can help in managing symptoms.**

## RESULTS OF DEMODEX INFESTATION



**68%**

**of patients over the age of 60 reported some discomfort from blepharitis and meibomian gland dysfunction<sup>(4)</sup>**

## SYMPTOMS AND SIGNS OF BLEPHARITIS

- Lid-margin inflammation or redness,
- Collarettes around the base of each eyelash,
- The thickening and cloudiness of the clear oil of the meibomian glands,
- Lash loss,
- Complaints of itching or a tickling sensation around or on the eyelids,
- And the presence of Demodex mites.

## DURATION

- Patients must understand that long-term lid hygiene is required as Demodex is a chronic condition requiring chronic therapy.
- The daily maintenance of the eyelid's hygiene with **Naviblef<sup>®</sup> TERP Daily Care** is recommended to daily remove secretion from the eyelids and eyelashes.

## THE MANAGEMENT OF DEMODEX INFESTATIONS

The management includes a combination of :

- **NAVIBLEF<sup>®</sup> TERP Intensive Care** cleansing foam
  - and with **Naviblef<sup>®</sup> TERP Daily Care for the Maintenance** and cleansing regimen
- } for periods of 4 weeks

Patients with Demodex are typically prescribed an eyelid cleanser such as **Naviblef<sup>®</sup> TERP Intensive Care for the first phase of attack** and for the maintenance **Naviblef<sup>®</sup> TERP Daily Care**, that contains **Terpinen-4-OL**.

## ADVICES FOR YOUR PATIENTS

- Cleanse the eyelids and eyelashes with **Naviblef<sup>®</sup> TERP Foams**.



## ATTACK



**naviblef<sup>®</sup>**  
**TERP**

**INTENSIVE CARE**

### DESCRIPTION AND INDICATIONS

**NAVIBLEF<sup>®</sup> TERP INTENSIVE CARE** contains a high concentration of Terpinen-4-ol, one of the components of tea tree oil, which thanks to its oily texture, helps to eliminate the most difficult secretions of eyelids and eyelashes.

**NAVIBLEF<sup>®</sup> TERP INTENSIVE CARE** contains Allantoin to help keep the skin hydrated.

**NAVIBLEF<sup>®</sup> TERP INTENSIVE CARE** has an improved formula which induces an efficient mechanical removal of severe ocular secretions and debris from eyelashes and eyelids.

These are caused by inflammatory conditions such as dryness, allergies, blepharitis and blepharoconjunctivitis, resulting from the presence of Demodex (eyelid mites) and bacterial infestations, dry eyes, contact lens wear... This foam can also be used to clean the base of the eyelashes and eyelid margins before and after surgery.

### COMPOSITION

**Malaleuca Alternifolia leaf oil (standardized at 96% of terpinen-4-Ol ) 1%, Anthemis Nobilis (Chamomille) Essential Oil 0,1 %, D-panthenol 1%, Allantoin 0,1 %, Taurine, Cocamidopropyl Betaine, Boric Acid, Tromethamine, Helichrysum Glycolic Extract, EDTA Disodium Salt, Sodium N-hydroxymethylglycinate, PEG-40 Hydrogenated Castor Oil, PPG-26 Buteth 26, Trideceth-9 and Purified Water.**

## MAINTENANCE



**naviblef<sup>®</sup>**  
**TERP**

**DAILY CARE**

### DESCRIPTION AND INDICATIONS

**NAVIBLEF<sup>®</sup> TERP DAILY CARE** contains Terpinen-4-ol, one of the components of tea tree oil, which, thanks to its oily texture, helps to eliminate secretions of eyelids and eyelashes. **NAVIBLEF<sup>®</sup> TERP DAILY CARE** contains Allantoin to help keep the skin hydrated. **NAVIBLEF<sup>®</sup> TERP DAILY CARE** is designed to treat irritated eyelids affected by pathologies such as dryness, allergies, blepharitis and blepharoconjunctivitis due to the presence of Demodex (eyelid mites) and/or bacterial infestations.

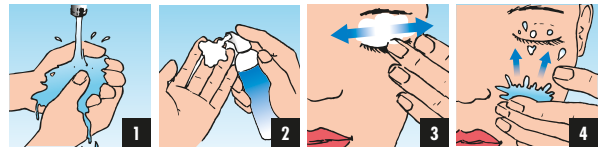
The effect of **NAVIBLEF<sup>®</sup> TERP DAILY CARE** is obtained through the mechanical removal of excessive oil, pollen, and other debris from the eyelids. In case of persisting secretions and residues, daily application is recommended. This foam can also be used to clean the base of the eyelashes and eyelid margins before and after surgery.

**NAVIBLEF<sup>®</sup> TERP DAILY CARE** has an improved formula that makes it suitable to be used as maintenance care, for patients who have followed the blepharitis treatment with **NAVIBLEF<sup>®</sup> TERP INTENSIVE CARE**.

### COMPOSITION

**Malaleuca Alternifolia leaf oil (standardized at 96% of terpinen-4-Ol ) 0,5%, Anthemis Nobilis (Chamomille) Essential Oil 0,1%, D-Panthenol 1%, Allantoin 0,1%, Taurine, Cocamidopropyl Betaine, Boric Acid, Tromethamine, Helichrysum glycolic extract, EDTA Disodium Salt, Sodium N-hydroxymethylglycinate, PEG-40 Hydrogenated Castor Oil, PPG-26 Buteth 26, Trideceth-9 and purified Water.**

## DIRECTIONS FOR USE



**1-** Before the application of the foam, wash your hands and then clean your fingertips with the appropriate **NAVIBLEF<sup>®</sup> TERP Foam** to be applied.

**2-** Press the delivery pump and place the foam on your clean fingertips. When used before or after surgery it is recommended to place the foam on sterile gauze. **Do not apply directly in the eyes.**

### IF YOU USE NAVIBLEF<sup>®</sup> TERP INTENSIVE CARE:

**3-** Close the eye and massage the eyelid and eyelashes with **NAVIBLEF<sup>®</sup> TERP Intensive Care**. Do not touch or open the eyes during the application. Let the foam dry before opening your eyelid to avoid the product entering the eye. Leave the product on for 3-5 minutes.

**REPEAT THIS TREATMENT 2 - 3 TIMES A DAY FOR A PERIOD BETWEEN 7 TO 14 DAYS, OR ACCORDING TO THE SPECIALIST'S ADVICE FOR MAXIMUM EFFICACY.**

### IF YOU USE NAVIBLEF<sup>®</sup> TERP DAILY CARE:

**3-** Close the eye and massage the eyelid and eyelashes with **NAVIBLEF<sup>®</sup> TERP Daily Care**. Do not touch or open the eye during the application. Leave the foam for approximately 60 to 80 seconds.

**REPEAT THIS TREATMENT 2 - 3 TIMES A DAY OR ACCORDING TO THE SPECIALIST'S ADVICE FOR AN EFFICIENT MAINTENANCE CARE AND GOOD HYGIENE OF EYELIDS AND EYELASHES.**

**4-** After each application of either **NAVIBLEF<sup>®</sup> TERP Daily Care** or **NAVIBLEF<sup>®</sup> TERP Intensive Care** rinse the eyelids and eyelashes with warm water.

**Note: Repeat the same steps for the other eye. It is recommended that patients with Demodex wash their hair using a tea tree oil shampoo. Not suitable for children under 6 years old. For children over 6 years old the application must be performed by an adult and only after your specialist's advice.**

## WHAT IS TERPINEN-4-OL (MELALEUCA ALTERNIFOLIA) ?



**NAVIBLEF<sup>®</sup> TERP** contains a high concentration of **Terpinen-4-ol**, one of the components of the tea tree oil, which, thanks to its oily texture, helps to eliminate the most difficult secretions of eyelids and eyelashes.

### HISTORY / TRADITIONAL USAGE



Tea tree essential oil has been used for almost 100 years in Australia for its antiseptic and anti-inflammatory actions. More than 80% of the world's tea tree oil is produced in Australia.

The Aborigines inhaled crushed leaves of tea tree to treat coughs and colds or used on wounds.

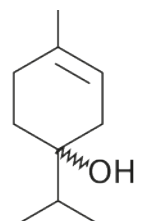
Legend has it that the oil with its medicinal benefits was considered so important that Australians soldiers were supplied tea tree oil in the World War II military kit to treat possible skin infections and to repel insects.

### COMPOSITION

**Terpinen-4-ol** is the principal active compound in tea tree oil responsible for the antimicrobial and anti-inflammatory activities.

This active compound is present in the essential oil at around 40% but in **NAVIBLEF<sup>®</sup> TERP** it is a standardized tea tree extract containing 96% of **Terpinen-4-ol**.

It is produced using a unique, solvent free, fractional distillation process which separates and concentrates the **Terpinen-4-ol**.



ATTACK

MAINTENANCE

MEDICAL DEVICE  
CLASS II A



naviblef<sup>®</sup>  
TERP  
INTENSIVE CARE

MEDICAL DEVICE  
CLASS II A



naviblef<sup>®</sup>  
TERP  
DAILY CARE

## A COMPLETE RANGE TO CARE FOR YOUR EYELIDS AND EYELASHES IN CASE OF BLEPHARITIS AND DEMODEX INFESTATION

- ✓ GOOD OCULAR TOLERABILITY\*
- ✓ NO ALTERATION TO THE PALPEBRAL SKIN
- ✓ NO ALTERATION TO THE CONJUNCTIVAL MUCOSA

Novax Pharma clinically tested the medical device NAVIBLEF<sup>®</sup> TERP INTENSIVE CARE in order to assess its ocular tolerability when used in the eye area.

A clinical evaluation was conducted on 20 healthy patients without medical contraindication. Patients used the product after closing the eyes, massaging it on the eyelids and eyelashes once every 2 days for a period of 14 days. During this period, the conjunctival and palpebral skin of patients were assessed. The observations were the following: NO SIGNIFICANT UNDESIRE EFFECTS, NO ALTERATION TO THE PALPEBRAL SKIN, NO ALTERATION TO THE CONJUNCTIVAL MUCOSA.

According to the observed clinical scores collected from the clinical evaluation, NAVIBLEF<sup>®</sup> TERP INTENSIVE CARE has proven to have good ocular tolerability: no significant undesired effects, alterations to the palpebral skin and conjunctival mucosa.

\* Mild irritation occurred in 2 patients after application but this cleared after a few minutes with no other effects observed.

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- (6) Hypersensitivity test - Novax Pharma internal data.
- (7) Skin irritation test - Novax Pharma internal data.
- (8) Citotoxicity test - Novax Pharma internal data.



Naviblef<sup>®</sup> TERP Intensive Care  
Naviblef<sup>®</sup> TERP Daily Care

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