

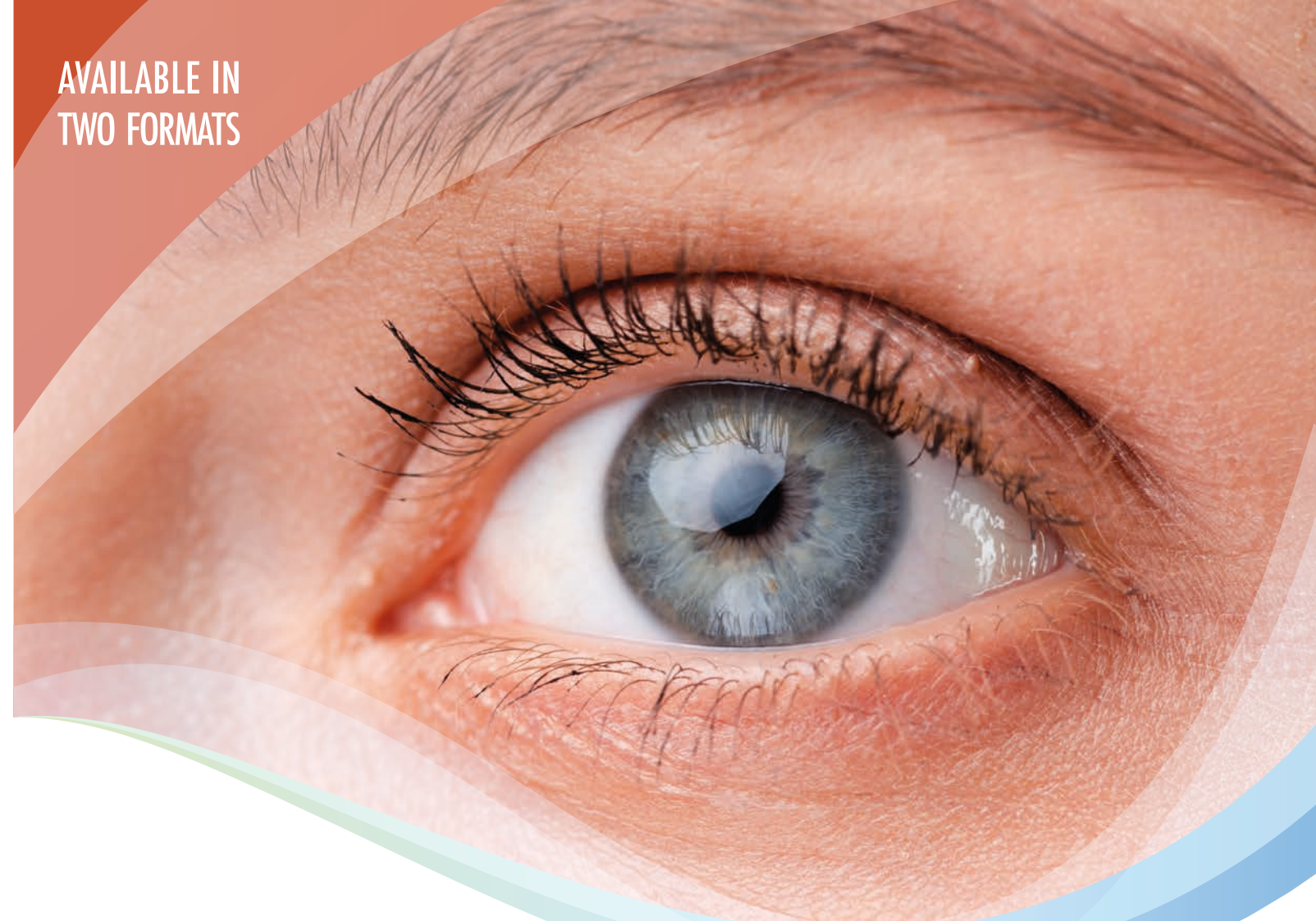
ATTACK



MAINTENANCE



AVAILABLE IN
TWO FORMATS



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® TTO 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 UNDESIRABLE 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® TTO 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.

BIBLIOGRAPHY

- (1) Pathogenic Role of Demodex (2010), Liu, Scheffer, Tseng.
- (2) Review of Ophthalmology®: Blepharitis Diagnosis Don't Forget Demodex (2012), M. Stephenson.
- (3) Facts About Blepharitis | National Eye Institute <https://nei.nih.gov/health/blepharitis/blepharitis>
- (4) The role of omega-3 dietary supplementation in blepharitis and meibomian gland dysfunction. Trans Am Ophthalmol Soc 2008;106:336-356 Macsai M.
- (5) Demodex blepharitis: clinical perspectives, Stephanie R Fromstein, Jennifer S Harthan, Joymani Patel, and Dominick L Opitz.
- (6) Hypersensitivity test - Novax Pharma internal data.
- (7) Skin irritation test - Novax Pharma internal data.
- (8) Cytotoxicity test - Novax Pharma internal data.
- (9) Tolerability test - Novax Pharma internal data.

NOVAX®
PHARMA

NOVAX® PHARMA
Le Coronado
20, Av. de Fontvieille
MC 98000 MONACO
www.novaxpharma.com

Navibler® TTO Intensive Care
Navibler® TTO Daily Care



Images diffusées sous licence de Shutterstock.com

The information reported here is meant to be used only by physicians.

88 N°8 TTO 18/11/00 12/03/2022

A FULL RANGE OF EYE CARE

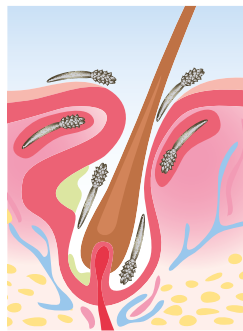


A natural way to help keep
your eyelids and eyelashes clean,
comfortable and healthy

NAVIBLEF®TTO 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 goes 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⁽⁴⁾

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®TTO 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®TTO Intensive Care** cleansing foam
 - and with **NAVIBLEF®TTO 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®TTO Intensive Care for the first phase of attack** and for the maintenance **NAVIBLEF®TTO Daily Care**, that contain Tea Tree Oil.

ADVICES FOR YOUR PATIENTS

- Cleanse the eyelids and eyelashes with **NAVIBLEF®TTO Foams**.

ATTACK



naviblef®
TTO
INTENSIVE CARE

DESCRIPTION AND INDICATIONS

NAVIBLEF®TTO Intensive Care is indicated for the **hygiene and mechanical removal of severe ocular secretions and debris from eyelashes and eyelids.**

These symptoms can be caused by inflammatory conditions resulting from blepharitis and blepharo-conjunctivitis, presence of bacteria or Demodex (eyelid mites), dry eyes, contact lens wearing or ocular surgery.

Through the mechanical action of the product, **NAVIBLEF®TTO Intensive Care** can help **reduce the risk of infection before and after ocular surgery caused by bacteria and/or Demodex present on eyelids and eyelashes.**

PROPERTIES

NAVIBLEF®TTO Intensive Care is a non-greasy and non-irritant formulation, **for topical use.**

COMPOSITION

Melaleuca Alternifolia (Tea Tree Oil) Essential Oil, Anthemis Nobilis (Chamomile) Essential Oil, D-Panthenol, Aloe Vera, Taurine, Chamomile aroma, Tris (Hydroxymethyl) aminomethane, Boric Acid, Disodium EDTA, Sodium N-hydroxymethylglycinate, Cocamidopropyl betaine, PEG-40 Hydrogenated Castor Oil, PPG-26 Buteth 26, trideceth-9 and purified Water.

MAINTENANCE



naviblef®
TTO
DAILY CARE

DESCRIPTION AND INDICATIONS

Maintaining a daily eyelid and eyelashes hygiene with **NAVIBLEF®TTO Daily Care** provides many benefits including the **reduction of dry, scratchy or irritated eyes symptoms.**

NAVIBLEF®TTO Daily Care effectively **removes excess oil, pollen and other debris from the eyelids** which increase the risk of irritation and blepharitis due to the presence of Demodex (eyelid mites), bacterial infestations or dry eye symptoms.

NAVIBLEF®TTO Daily Care is recommended to be used a maintenance care, and for patients who have followed the attack phase with **NAVIBLEF®TTO Intensive Care.**

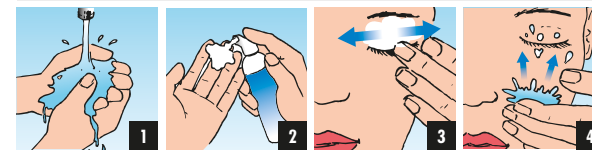
PROPERTIES

NAVIBLEF®TTO Daily Care is a non-greasy and non-irritant formulation, **for topical use.**

COMPOSITION

Melaleuca Alternifolia (Tea Tree) Essential Oil, Anthemis Nobilis (Chamomile) Essential Oil, D-Panthenol, Allantoin, Taurine, Cocamidopropyl betaine, Polysorbate 80, Boric Acid, Disodium EDTA, Tris (hydroxymethyl) aminomethane, Sodium N-hydroxymethylglycinate 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®TTO 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.

IF YOU USE NAVIBLEF®TTO INTENSIVE CARE :

3- Close the eye and massage the eyelid and eyelashes with **NAVIBLEF®TTO 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 OF 7 TO 14 DAYS, FOR MAXIMUM EFFICACY.

IF YOU USE NAVIBLEF®TTO DAILY CARE :

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

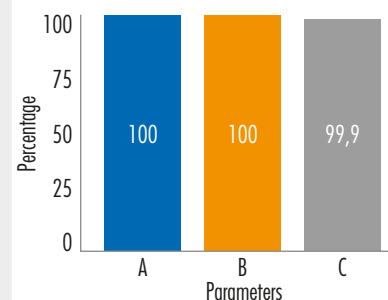
REPEAT THIS TREATMENT 2 - 3 TIMES A DAY FOR LONG-TERM MAINTENANCE AND GOOD HYGIENE OF EYELIDS AND EYELASHES.

4- After each application of either **NAVIBLEF®TTO Daily Care** or **NAVIBLEF®TTO 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.

TEA TREE OIL ALLEVIATES DEMODEX INFESTATIONS AND ASSOCIATED SYMPTOMS

CLINICAL EVALUATION OF THE OCULAR TOLERABILITY OF NAVIBLEF®TTO INTENSIVE CARE = WORST CASE



- A. Alterations for the conjunctival mucosae (conjunctivitis and chemosis)
- B. Palpebral skin alterations (vasodilatation, edema and blepharitis)
- C. Occurrence of slight undesired effects (lacrimation, burning, photophobia)

SEVERITY* SCORE A, B, C

NO PRESENT : 0
Present slightly : +2
Present evident : +4

OBJECTIVES OF THE STUDY

The **NAVIBLEF®TTO Intensive Care** medical device is investigated for assessing its ocular tolerability when used in the eyes area. The objective of the current clinical evaluation is assess whether the product in itself could cause problems of ocular irritation related to its use. Irritation related to its use and risks associated tolerability on conjunctival mucosae and palpebral skin.

TYPE OF THE STUDY

Group of 20 healthy patients both female and male

- 3 of them have sensitive eyes
- 10 of them have sensitive eyes and are contact lenses wearers
- 7 of them are healthy

DURATION OF THE TEST: 14 DAYS

Patients used this product after closing the eyes, massaging it on the eyelid and eyelashes and waiting the product dried before opening the eye to avoid the product enter onto it. The foam has been left for at least 15 to 20 minutes, the duration longer than indicated (3 to 5 minutes). After each application patients rinsed eyelashes and eyelids with warm water. 1 time each 2 days for a period of 14 days.

AVERAGE OF RESULTS FROM TOLERABILITY TEST

No effects on points A and B (100 % of tolerability).

Point C: Only 2 person have felt occurrence of slight and no significant undesired effects (lacrimation, burning, photophobia) in a severity* of 1 and 3 (99,9 % of tolerability).

CONCLUSIONS

According to the observed clinical scores during the clinical evaluation, we can state that the medical device class II A, the **NAVIBLEF®TTO Intensive Care** has prove to have a good ocular tolerability, in fact no significant palpebral skin alterations point A and alterations for the conjunctival mucosae point B have been observed.