

BUSTILENE

CREAM PAIN RELIEF PREMENSTRUEL BREAST – MASTODYNIA

Symptomatic treatment of mastodynia during premenstrual syndrome – premenstrual breast pain

What is Premenstrual Syndrome - Signs & Symptoms of Mastodynia?

Premenstrual syndrome is probably the most common functional discomfort reported by women ; it is most often accompanied by a deterioration in the quality of life. Premenstrual syndrome generally appears gradually during the genital life (4 times more frequent after puberty), or following a triggering circumstance : childbirth or abortion, genital infection or psycho-emotional shock. It is very likely related to cyclic hormonal changes.

Three types of well-known symptoms are almost always encountered :

- breast tension or mastodynia;
- abdomino pelvic tension (abdominal bloating);
- psychic tension.

Mastodynia is defined as uni or bilateral breast pain. It is a frequent symptom, women often generated by an estroprogestative imbalance. Left untreated, it can lead to a mastopathy that, although benign, is one of the risk factors for breast cancer.

Apart from these common symptoms, each patient's own reaction may be externalized by temporary conditions, such as migraines, digestive disorders, transit disorders, heaviness of the lower limbs, etc. The severity of the intensity of the symptoms varies according to the cycles.

The severity of the intensity of the symptoms varies according to the cycles. The benefit / risk ratio of drug treatments that can combine several active ingredients (hormones, antidepressants, anxiolytics, diuretics) is generally considered unfavorable and non-medicinal treatments (so-called natural medicines, dietary rules, ...) have not been proven their effectiveness.

Indication :

BUSTILENE helps to relieve the painful signs and symptoms of mastodynia – pain relief premenstrual breast in a patient with premenstrual mastodynia.

BUSTILENE is intended for adult women (aged 18 years and older) with signs and symptoms of mastodynia (premenstrual breast pain).

Clinical Benefits / Performance / Mechanism of Action:

Thanks to its sliding feature adapted to sensitive tissues and its biomechanical properties, **BUSTILENE** avoids the shearing effect of massage.

BUSTILENE limits water insensitive loss (IPE) and promotes a normal return of the underlying microcirculation, restoring good tissue oxygenation and a return to normal physiological processes.

By its mode of action, **BUSTILENE quickly and significantly reduces the symptomatology of premenstrual syndrome, and mainly breast tension or mastodynia**

BUSTILENE applied locally by prolonged stroke massage.

BUSTILENE is a medical device that has proven clinical effectiveness*. Patent filed and published.

Use Instructions:

Before & after application, it is recommended to wash your hands thoroughly. **BUSTILENE** is suitable for all skin types.

Apply twice daily (morning and evening) **BUSTILENE to the breasts** during the days preceding the presumed date of the periods.

"Apply a dab of cream on each breast at least twice a day morning & evening, and more if necessary. The application will be done by an extended stroke massage ".

Warnings / Precautions:

The only possible contraindication to **BUSTILENE** is a known allergy to one of its constituents. Due to the absence of clinical study, this cream is not to be used on pregnant or breastfeeding women, or with a history of breast or oncological surgery.

BUSTILENE is for external use only and should not be used near the eyes

BUSTILENE has no side effects under normal conditions of use.

BUSTILENE should not be used in individuals with hypersensitivity to any component.
BUSTILENE should not be used in case of skin lesion.
BUSTILENE should not be applied in combination with other products in the same area.
Reserved for adults. Keep out of the reach of children.

Side effects :

In the case of an allergic reaction, discontinue treatment and consult a doctor
Expected side effects may include itching, pruritus / erythema ...

Any serious incident occurring in connection with this medical device must be notified without delay to the manufacturer and the competent authority (ANSM).

Storage / Handling / Disposal:

BUSTILENE should be stored at room temperature and away from any source of heat and light.
Do not use beyond the expiration date on the tube bend and on the case.
BUSTILENE must be disposed of in accordance with the waste treatment conditions.

Composition :

Oxidized triglycerides (TGO) from plant essential fatty acids of natural origin (corn oil), allantoin, Distilled water of pink, Solubilizer LRI, Aristoflex stroke Microcare PHC, Fragrance, Water QSP

This product is of natural origin and does not contain alcohol.

Identification of the medical device:

Name: **BUSTILENE**
Medical Device Class I



Presentation : tube of 40 gr

Identification of economic operators (manufacturer / distributor):

Manufacturer : Laboratoires Carilène - 7, rue du Chant des Oiseaux - 78360 Montesson- France

Distributor: XXX

Version of the leaflet:

Last revision date: 29/11/2018 – Original Version: V1

***Clinical Investigational:** Evaluation of the efficacy and tolerance of a medical device on the improvement of signs and symptoms of mastodynia during premenstrual syndrome – Pain related to breast tension – Study under gynaecological control – Clinical Studie in open; intra-individual; in monocentric. Subject declaring having already presented regular signs of mastodynia, rhythmmed by menstruation.



« Consult the user manual »



« Medical Device complies with the essential requirements of Directive 93/42/EEC and Amendments »



« Batch number »



« Use until »



« Manufacturer »