Biatain[®]Ibu Soft-Hold **Coloplast**

Biatain Ibu Soft-Hold foam dressing with ibuprofen (0.5 mg/cm²)



Instructions for use 23321818 Version 1

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Indications

The product is intended for moist wound healing and exudate management of painful wounds

The product:

- is indicated for a wide range of low- to highly exuding wounds. This includes acute wounds such as second degree burns, postoperative wounds and traumatic wounds; and chronic wounds such as leg ulcers, pressure ulcers and non-infected diabetic foot ulcers

- may reduce wound pain caused by tissue damage
- is suitable for use in combination with compression therapy.

Contraindications

Do not use the product if the user (patient or health care professional) has a known hypersensitivity to ibuprofen or any of the ingredients, acetylsalicylic acid or other NSAIDs, especially when associated with a history of asthma, rhinitis, or urticaria.

Do not use the product during pregnancy.

Do not use the product on children under 12 years of age except on the advice of a health care professional.

Do not exceed the stated dose.

Do not use the product on donor sites.

Information

The product is a sterile, single use, polyurethane foam dressing suitable for wounds that are difficult to bandage. A secondary dressing is needed for fixation.

The product:

- contains ibuprofen (0.5 mg/cm²) homogeneously dispersed throughout the foam. Ibuprofen is released into the wound bed when in contact with wound exudate - may be left in place for up to 7 days depending on the amount of exudate, dressing conditions, and type of wound

- can be used up to a maximum of 1200 cm² at each dressing change, e.g.12 dressings of 10 cm \times 10 cm each. The dressing should not be changed more than twice daily corresponding to a maximum daily use of 2400 cm²

- can be used continuously for up to 6 weeks as long as clinically indicated

The product consists of:

- a vapour permeable top film which is bacteria-proof and waterproof

- an absorbent polyurethane foam with ibuprofen
- a partially adherent layer
- a clear protective film

Ibuprofen may in rare cases cause serious alleraic reactions. If you experience a suspected allergic reaction, or any other side effects, please contact your health care professional.

Coloplast accepts no liability for any injury or loss that may arise if this product is used in a

manner contrary to Coloplast's current recommendations.

A health care professional should frequently inspect and manage infected wounds, diabetic wounds and wounds which are solely or partially caused by arterial insufficiency, in accordance with local auidelines.

Do not use the product with oxidising solutions, e.g. hypochlorite and hydrogen peroxide solutions. Ensure that any other evaporating solution is completely dried off before applying the product.

The use of cleansing agents other than physiological saline solution or tap water in combination with the product has not been investigated.

Remove the product prior to radiation treatment or examinations that include X-rays, ultrasonic treatment, diathermy, microwaves, or MR scanning.

For infected wounds, including erysipelas, an appropriate treatment must be used.

Keep out of reach of children.

Do not use if package is damaged.

Keep away from sunlight.

Store in a horizontal position.

Warnings

Re-use of the single use product may create a potential harm to the user. Reprocessing, washing, disinfection and/or sterilisation may compromise product characteristics, causing additional risk of physical harm or infection to the user.

How to use Preparation

Cleanse the wound and periwound skin in accordance with local guidelines, e.g. lukewarm water or physiological saline solution.

Gently dry the periwound skin.

If any film, cream, ointment or similar product is used, allow the periwound skin to dry before applying the product.

If the wound is low-exuding, the product may be moistened with sterile physiological saline solution before application.

Application

Select a product where the foam overlaps the wound edge by a minimum of 1-2 centimetres

For bigger sized products, e.g. 20 cm x 20 cm, the foam must overlap the wound edge by a minimum of 2 centimetres.

Ensure aseptic handling during application. Avoid touching the non-printed side of the foam during application. Use forceps, if necessary.

Remove the clear protective film.



Apply the non-printed side of the foam towards the wound.

A secondary dressing is needed for fixation. Do not cover the entire product with an occlusive secondary dressing.

Removal

The product should be changed when clinically indicated, when visible signs of exudate approach the edge of the foam or after 7 days.

Gently lift the corners of the product away from the wound and remove the product.

Disposal

The product is intended for single use only and should be disposed of in accordance with local guidelines, e.g. with normal household waste.

Do not flush the product down the toilet.

Symbols

- Do not use if package is damaged. \bigotimes
- 8 Not made with natural rubber latex.

Sterilised using irradiation (R)



