Public Summary

Summary for ARTG Entry:	151997	Coloplast Pty Ltd - Biatain Ibu Non-Adhesive Foam Dressing - Dressing, high-absorbent, foam/sheet/liquid/powder, non-hydrophilic gel-forming

ARTG entry for	Medical Device Included Class III
Sponsor	Coloplast Pty Ltd
Postal Address	Suite 1 Level 7, 1 Peters Avenue, Mulgrave, VIC, 3170 Australia
ARTG Start Date	30/04/2008
Product Category	Medical Device Class III
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Coloplast AS	Holtedam 1 , Humlebaek, 3050 Denmark

Products

1 . Biatain Ibu Non-Adhesive Foam Dressing - Exudate-absorbent dressing, non-gel

Product Type	Single Device Product	**Effective Date**	14/07/2023

GMDN	44970 Exudate-absorbent dressing, non-gel
Functional Description	The dressing is a sterile, single use, polyurethane foam dressing which contains ibuprofen (0.5 mg/cm²) homogeneously dispersed throughout the foam. Ibuprofen is released into the wound bed when in contact with wound exudate and may be left in place for up to 7 days. The dressing should not be changed more than twice daily corresponding to a maximum daily use of 2400 cm² and can be used continuously for up to 6 weeks as long as clinically indicated.
Intended Purpose	Biatain Ibu Non-Adhesive Foam Dressing is intended for moist wound healing and exudate management of painful wounds; and is indicated for a wide range of low to highly exuding wounds including acute wounds such as second degree burns, donor sites, postoperative wounds and traumatic wounds; and chronic wounds such as leg ulcers, pressure ulcers and non-infected diabetic foot ulcers. The dressing may reduce wound pain caused by tissue damage; and is suitable for use in combination with compression therapy. Non-adhesive dressings are suitable for use on fragile skin due to the absence of adhesive.
Variant information	Size (cm) 10 x 10 Size (cm) 10 x 20 Size (cm) 15 x 15 Size (cm) 20 x 20

Specific Conditions

No Specific Conditions included on Record

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