

BioFil[®]-AB Particles

Sterile Medicated Collagen Particles

A cost effective solution for Chronic wounds & Diabetic foot ulcers

Introduction

Surgeons who treat chronic non-healing ulcers including diabetic ulcers and pressure ulcers etc., face a real challenge when it comes to the closure of the wounds due to inadequacies of conventional treatment protocols and complexities of ulcers. The result is catastrophic and traumatic. Quality of life suffers as many patients get into the stage of amputations especially in the case of diabetic foot ulcers. It is for this reason, useful biomaterials like collagen play a very important role in the wound management to alleviate the sufferings of millions of victims in this category.

An attempt has been made to offer the collagen material in porous lyophilized particle form with a very powerful and effective antimicrobial combination of mupirocin and metronidazole in suitable proportions for providing cost-effective solutions in the management of chronic wounds including diabetic foot ulcers.

Collagen

Collagen is an extra cellular matrix protein playing a major role in connective tissue. It is the most abundant protein in humans and performs multiple functions. In fish, the largest concentration of collagen is found in the skeleton, fins, skin and air bladder. Collagen as a biomaterial and its role in wound management is a well-documented subject. Collagen encourages wound healing through the deposition and organization of freshly formed fibers and granulation tissues in the wound bed and thus creating a very conducive environment to wound healing.

Mupirocin-USP

Topical Mupirocin is very effective against *S.aureus* and this drug is invaluable in the eradication of staphylococci. (Oxford Text Book of Medicine, 3rd edn, Vol 1, P 526)

Mupirocin is an antibiotic used in the treatment of various bacterial skin infections. (Martindale, The Extra Pharmacopoeia, 31st edn, P251)

Mupirocin is an antibacterial agent and active against a wide range of gram +ve bacteria. (PDR 55th edn, 2001, P 3075)

Metronidazole-IP

Metronidazole topical cream is indicated in the treatment of Gram -ve bacterial infections. (PDR 55th edn, 2001, P 129)

Topical formulations of Metronidazole has been proven effective in various skin disorders. (Martindale, The Extra Pharmacopoeia, 31st edn, P624)

Metronidazole is a member of the imidazole class of antibacterial agents. (PDR 55th edn, 2001, P 1115)

Metronidazole has been used to treat anaerobic infections for about 30 years. Most clinically important anaerobes remain extremely sensitive to it. (Oxford Text Book of Medicine, 3rd edn, Vol 1, P575)



Role of collagen in wound healing

- ▶ Stops Bleeding (Hovig et al., 1968)
- ▶ Helps in wound Debridement by attracting Monocytes (Postlewaithe and Kang, 1976)
- ▶ Provides a Matrix for Tissue and Vascular Growth (Kleinman et al, 1981a)
- ▶ Attracts Fibroblasts and helps in Directed Migration of cells (Dunn and Ebendal, 1978)
- ▶ Binds with Fibronectin, which promotes cell binding (Kleinman et al., 1981b)
- ▶ Supports growth (Morykwas et al., 1989), differentiation and migration (Emerman and Pitelka, 1977) of Keratinocytes
- ▶ Helps in deposition of Oriented and Organized Fibres (Doillion et al., 1984), which increase the integrity of the Tissue.

BioFil[®]-AB Particles

Description

BioFil[®]-AB Particles are primarily a Type 1 collagen (fish origin) in lyophilized particle form with Mupirocin USP 2% w/w and Metronidazole IP 1% w/w of specified volumes. It is Gamma Sterilized and supplied in convenient cold seal blister packing. **BioFil[®]-AB** Particles possessing good absorbing characteristics are non-toxic, non-allergenic and non-immunogenic.

Indications

- ✓ Non-healing ulcers
- ✓ Venous ulcers
- ✓ Infected and non-infected wounds
- ✓ Diabetic foot ulcers
- ✓ Traumatic wounds
- ✓ Minimal to heavily draining wounds
- ✓ Pressure ulcers
- ✓ Surgical wounds
- ✓ Tunneled and undermined wounds

Application Methodology

- ✓ Assess, debride and clean the wound according to your protocols
- ✓ Apply **BioFil[®]-AB** Particles sufficiently to cover the wound surface
- ✓ With a heavily draining wound : Cover with an absorbent dressing and change if necessary
- ✓ With a minimal draining wound : Cover with a secondary non-absorbent dressing and change as required
- ✓ Remove the secondary (cover) dressing daily as indicated by the amount of draining
- ✓ If secondary dressing is adhered to the wound, irrigate with saline solution until dressing loosens and lift gently
- ✓ Irrigate the wound with saline to cleanse the area thoroughly
- ✓ Reapply **BioFil[®]-AB** Particles as before



Precautions & Warnings

- ✓ Wound may appear larger during the first several days of treatment due to the reduction of edema
- ✓ An increase in drainage may be seen in the first several days of treatment
- ✓ Treatment of the underlying conditions (Venous or arterial flow, external pressure etc.,) as well as nutritional support should proceed concurrently with the use of **BioFil[®]-AB** Particles
- ✓ All opened and unused portions of **BioFil[®]-AB** Particles must be discarded
- ✓ Avoid on patients hypersensitive to Collagen, Mupirocin and Metronidazole
- ✓ Avoid topical agents like Povidone Iodine, H₂O₂ and Sodium Hypochlorite for cleansing the wound as their toxicity level may hamper the new tissue growth
- ✓ **BioFil[®]-AB** Particles is a single use product, which should not be resterilized

Storage

BioFil[®]-AB Particles should be stored in a dry place at temperature not exceeding 25°C. Do not freeze.

BioFil[®]-AB Particles are Sterilised by irradiation with a shelf life of 2 years.

Availability

BioFil[®]-AB Particles is available in convenient volumes of 5ml, 10ml & 15ml.

Ordering Information

CODE	DESCRIPTION	UNITS
BMPP 1002-05	BioFil[®]-AB Particles, 5ml vial	Box of 5
BMPP 1003-02	BioFil[®]-AB Particles, 10ml vial	Box of 2
BMPP 1004-02	BioFil[®]-AB Particles, 15ml vial	Box of 2



Manufactured by:

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