

## TECHNICAL DATA SHEET BIOSPRAY®

### DESCRIPTION

BIOSPRAY® is a collagen powder with atomiser.  
It is a medical device for self-medication not subject to medical prescription.

### COMPOSITION

Equine collagen  
Excipients: modified rice starch, miglyol. Solvents and propellant: permitted, s.q.

### INDICATIONS FOR USE

Treatment of sunburn, minor burns, skin irritation, superficial wounds and ulcers, nappy and incontinence rash, skin abrasions and grazes; haemostat.

Notwithstanding its excellent haemostatic properties BIOSPRAY® is not intended to replace ligation or direct compression procedures in case of heavy bleedings. Anti-clotting therapies do not interfere with BIOSPRAY® use.

### CONTRAINDICATIONS

DO NOT USE ON GROSSLY INFECTED WOUNDS

There are no contraindications in the use of BIOSPRAY® unless known hypersensitivity to the collagen itself.

Do not use the in patients with known family history of auto-immune diseases, history of anaphylactoid reactions or known hypersensitivity to collagen or any of the ingredients, or in subjects undergoing desensitization therapy to meat products.

Being a non-allergic product no sensitization phenomena nor side effects have ever been reported.

The use as haemostat must not replace, in case of heavy bleedings, the normal procedures of ligation or direct compression performed under strict medical or para-medical control.

### USE DURING PREGNANCY OR NURSING

The product is not systemically absorbed, therefore it can be used even during pregnancy or nursing.

### MEDICAMENTOUS INTERACTIONS

No medicamentous interactions are known or have ever been reported.

### DIRECTIONS FOR USE

Container under pressure, do not use if the container is damaged.

SHAKE WELL BEFORE EACH USE

Do not use after expiry date. The expiry date refers to an integral package, suitably stored.

The device can be used after first use until exhaustion of the product.

Use BIOSPRAY® after cleansing and disinfection of the lesion.

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It is recommended not to use the product associated to substances or drugs that can provide a barrier thus vanishing the product activity.

It is important, prior to use BIOSPRAY<sup>®</sup>, to remove eventual necrotic or purulent tissues.

Keep the can at about 15 cm distance from the lesion and briefly spray during one or two seconds over all the wounded area. The product supply, not respecting the suggested minimum distance, can cause a freezing sensation that disappears quickly without skin damages.

If need be, after the application of BIOSPRAY<sup>®</sup>, protect the lesion with a band-aid or a gauze. In children, skin folds or napkins act as natural bandage.

The incidental excess of sprayed product on the skin, even if not injured, may be eliminated without affecting the efficacy of the product. No need to remove, during each application, the residual product previously sprayed.

No sensitization phenomena have ever been reported following the topical use of the product.

#### **WARNINGS AND PRECAUTIONS**

Container under pressure.

Keep the product in a dry place, away from heat sources.

Protect against sunlight and do not expose to temperatures above +50°C.

Do not puncture or incinerate the can, even after use.

Do not spray on naked flames or on smouldering corpses.

Keep away from all sources of ignition.

Do not smoke during use.

Do not use in confined spaces.

Environmentally friend; no ozone depleting.

Do not environmentally dispose the container after use.

Do not spray the product into eyes and ears; avoid inhalation.

KEEP AWAY FROM THE REACH OF CHILDREN

#### **ADVERSE EVENTS**

No sensitization phenomena have ever been reported following the topical use of the product.

No side effects or undesirable effects have ever been revealed or reported.

#### **CLINICAL EVALUATION**

The efficacy and tolerability of BIOSPRAY was verified through clinical trials limitedly to the recommended indications.

The clinical evaluations were performed at the Burns Centre of the Dermatology and Venereal Diseases Unit of the University of Pisa and at the Dermatology Clinic of the same University in comparison with a marketed product constituted of colloidal silver, and using batches.

The clinical evaluation confirmed the excellent haemostat and wound healing properties of collagen, already known from literature, in the lack of any undesired sensitization.

### 3 – Biospray Technical Data Sheet

The comparative study performed aimed to evaluate the efficacy and tolerability BIOSPRAY®. The investigation involved 40 patients aged between 19 and 76, suffering from acute skin lesions and chronic skin wounds at low thickness.

Were excluded from the investigation those lesions showing clinical signs of infection and those patients that were incapable to follow the treatment.

Patients were allocated to the two study groups following an alternate random system:

- a) BIOSPRAY® collagen                      20 patients
- b) colloidal silver spray                    20 patients

The observation time lasted 4 weeks, or less whenever healing occurred first.

No relevant technical inconveniences occurred when spraying the active principle that proved regular and repetitive during the whole treatment period. The BIOSPRAY® application was repeated on the wounds – after appropriate cleansing – with an average frequency of 3-6 days. The removal of the medication was painless and made by simply using a gauze imbibed in saline solution.

During the whole period of treatment with BIOSPRAY® no remarkable side effects were noted on the cured areas. Healing time was significantly reduced after the use of BIOSPRAY® collagen in comparison to that of the control medication, with an average healing rate of 8.2 days.

The active principle (type I heterologous collagen) of the product constituted one of the essential factors during the process of tissue repair. The spray form administration of the product is optimal for its use in emergency and first aid in the traumatology of acute lesions but also in healing chronic lesions at low thickness, as demonstrated by the results generated by the clinical evaluation.

#### **PRECAUTIONS FOR STORAGE**

Keep the product in a dry cool place, away from heat sources.

Protect from sunlight and do not expose to temperatures above +50°C.

#### **RE-USE OF THE PRODUCT**

After each usage close carefully the container by means of the closing cap.

In case of imperfect atomisation of the powder remove the nozzle and cleanse the valve by a simple wash with lukewarm water. Dry the nozzle and place it in its original position, directing the air supply outwards.

#### **PRESENTATION**

75 ml or 50 ml aluminium cans

The device is sterile.

#### **MANUFACTURER**

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