

Information for Use. Read carefully!



BLOODCARE

Sterile absorbable haemostat based on oxidised cellulose

Manufacturer: LIFE LINE plus s.r.o. Hlavní 131, Brno, Česká Republika
Composition: oxidised cellulose (polyanhydroglucuronic acid 100%)
Indication Group: Haemostat

Characteristics:

BLOODCARE is a highly efficient medical device designed to stop capillary and/or venous bleeding upon surgical interventions. The active substance is defined as oxidised cellulose, and is available in the following variations:

- Flat form:

- With a woven structure - **Matrix**, which can be sutured
- With a knitted structure - **Net**
- With a fibrous structure - **Wad**

- Powder form:

- **Powder**
- **Spray**, powder suspension in a medical grade propellant.

The material is fully absorbable by the organism.

Indication:

BLOODCARE (excluding the Spray form) is used as an adjunct treatment to help haemostasis in stopping capillary bleeding, and bleeding from parenchymatous organs and resection areas, in surgical procedures, whenever conventional methods of haemostasis such as ligation are inadequate, not effective or not applicable.

In dental praxis, it is used to arrest prolonged post extraction capillary bleeding.

It is suitable for use in general and digestive surgery, plastic surgery, orthopaedics, gynaecology, urology, stomatology, and other surgical branches.

A definite advantage is the ability to fix the material by suture – applicable for Matrix and Net forms.

Due to the content of carboxyl groups which ranges from 16% to 24%, on application oxidised cellulose has a significant bacteriostatic and bactericidal effect on the wound site. The ability of the active substance to increase fibroblasts activation also accelerates the healing process; because of this **BLOODCARE** is also used as a medical device to hasten the healing of topical wounds such as lacerations, leg ulcers, decubitus etc.

BLOODCARE spray, a non-sterile variant of the range, is designed for use by non-medical professionals for the treatment of minor topical superficial bleeds.

Dosage and Method of Use of BLOODCARE (excluding the Spray form):

After opening the outer pouch (excluding the Spray form), take out the inner, sterile pouch, in which the requested form and size of **BLOODCARE** is kept.

The flat forms of the material can be adjusted to required dimensions by sterile instruments, and then applied on to the bleeding area.

The powder form is spread directly on to a bleeding area by pressing the sides of the bottle, or is delivered on the bleeding site through the applicator.

Saturated with blood, the material creates brownish-coloured 'mass' that should not be removed - it will be fully absorbed provided it is fully saturated by blood.

Haemostasis starts immediately, and the full haemostasis is achieved within 2 minutes. If the blood still slightly oozes through after application, another layer of the flat form (Matrix, Net or Wad) could be applied, or if BLOODCARE powder used additional quantity applied.

The Matrix or Net forms may be fixed to the tissue with stitches if required.

Should the material be washed off by a pressure bleed, this indicates an inappropriate use since BLOODCARE is designed to stop bleeding of a non-pressure character only.

When BLOODCARE is to be applied on to non-responding wounds, first the wound needs to be disinfected using a common procedure, and then the wound should be treated with an adequate amount of the BLOODCARE form (excluding Spray form) then secured with a dressing or similar material.

The active substance layer once saturated with blood and/or secrete will be absorbed by the tissue. Until the healing process is finished, the BLOODCARE layer should be repeatedly applied depending on how much the wound “weeps”. The covering dressing can be changed if necessary, usually when applying additional BLOODCARE.

Dosage and Method of Use of BLOODCARE (Spray form):

Before using BLOODCARE spray clean and disinfect the wound if necessary applying standard procedures. Dry the area around the wound. Shake the can well, remove the covering cap, and hold the can upright. Apply the required amount of BLOODCARE powder by spraying fluently on to the bleeding area from a distance of 10-15 cm at minimum for 2-3 seconds, or until the wound is smoothly covered with the Powder layer so that the bleeding stops. Do not remove the layer saturated with blood. Optionally, use a plaster or bandage to cover the wound if necessary.

Contraindications:

BLOODCARE is not designed to stop pressure bleeding.

BLOODCARE haemostats should not be used:

- for implantation in bone lesions, such as fractures because of potential interference with callus formation and a theoretical chance of cyst formation.
- in conjunction with methyl methacrylate adhesives because their presence may reduce the adhesive strength of the bonding agent to bone.
- around the optic nerve and chiasm respectively.
- should not remain in contact with other neural pathways, where extra pressure induced by the swelling of the absorbable haemostatic material may affect neural pathway function.
- for adhesion prevention.
- on non-haemorrhagic serous oozing surfaces, since body fluids other than whole blood, such as serum, do not react with the product to produce a satisfactory haemostatic effect.
- inside the blood circulatory system to avoid the passage of loose fragments of the product through blood salvage system filters. The presence of product fragments may lead to partial or full obstruction of the vasculature system.

After application on to the bleeding site, full saturation of the material with blood must be achieved to avoid a potential risk of granuloma formation – foreign body reaction.

Special Warnings:

The preparation need not be removed off the wound surface after application. It is well tolerated by the tissue, and supports the healing process.

In order to get the material resorbed in the application site, allow a full saturation with blood.

All BLOODCARE forms should be used by trained and skilled personnel only, except the BLOODCARE spray which has been developed for use by non-medical professional for the treatment of minor superficial injuries.

Interactions:

No interactions of active substance BLOODCARE with drugs have been reported, nor any other interactions.

Usage during Pregnancy and Lactation:

As far as is known, the active substance of the BLOODCARE forms can be applied with no risk to foetus during pregnancy and lactation period.

Adverse Reactions:

No adverse reactions/side effects have been reported.

Overdosage:

No cases of over dosage have been reported.

Storage:

BLOODCARE Forms should be stored in a dry room at room temperature (preferably between -20°C and +25°C). For long-term storage, it is recommended that the forms be stored at below 20 °C.

Do not expose to direct light and radiant heat.

Changes in colour of the active substance indicates incorrect storage, however these changes have no negative impact on the haemostatic properties.

BLOODCARE spray should be stored at temperatures below 40°C and must not be stored alongside organic solvents, acids or other aggressive or poisonous substances.

Keep out of reach of children.

Warning:

The preparations should not be used after the expiry date indicated on the packaging! If opened in a sterile environment, the preparation can be used repeatedly. If opened in a non-sterile environment, the material becomes non sterile, and could be used for superficial/external injuries only.

BLOODCARE Forms (matrix, net, wad & powder) are sterilised by gamma irradiation.

Do not re-sterilise!

BLOODCARE spray is not sterilised!

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