

HEMA LIMIT

Oxidised - cellulose based haemostat

HEMA LIMIT powder^s



Haemostatic
powder
form/sterile

HEMA LIMIT matrix

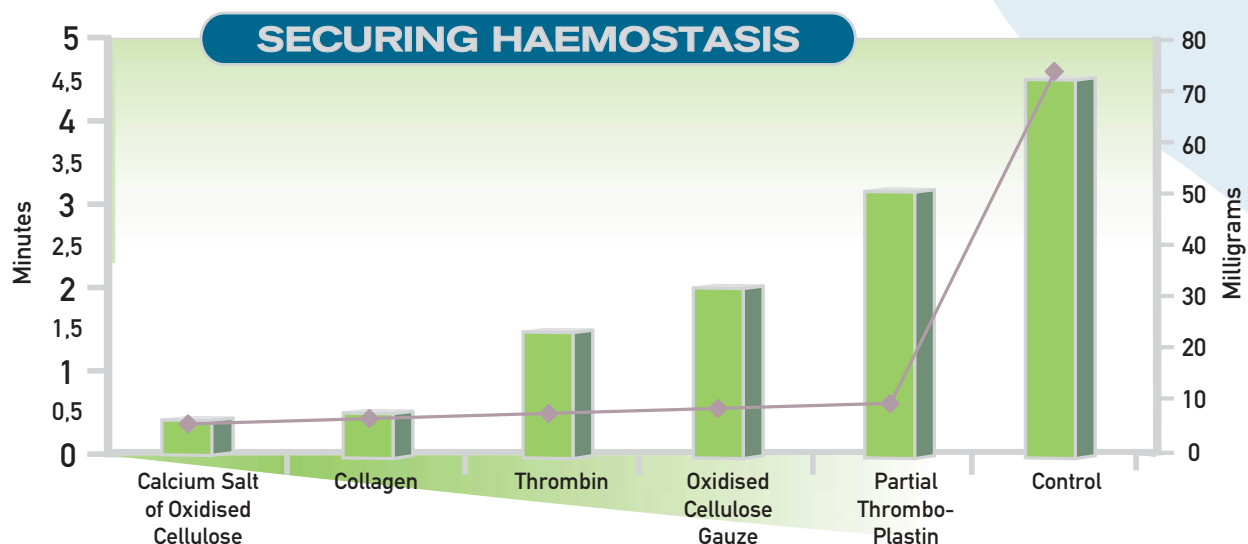
Haemostatic
flat form
with textile
structure/sterile



How is it made? Hema Limit is produced by selective oxidation of high-quality cotton material (99% of cellulose content at minimum). The process selectivity lies in the fact that predominantly alcoholic group on 6th carbon of basic building unit is oxidized and carboxyl is formed (-COOH), whose content is maintained at 16-24 volume % according to USP. From the chemical point of view it is polyanhydroglucuronic acid (used for Hema Limit matrix), whose acidity is decreased by neutralization to calcium salt (used for powder form). As free carboxyl groups are a carrier of oxidized cellulose bactericidal effect, only a part of those groups is calcium bound, residual ones are free.

What is it used for? Excellent haemostatic agent to arrest bleeding at surgical procedures.

How does it work? Hema Limit has a significant effect on starting the haemocoagulation process, and accelerates the blood coagulation in several ways. While applied, Factor VII is activated as well as the thrombocyte activation is initiated by tissue factor. Due to anionactive characteristics of oxidized cellulose, HEMA LIMIT is able to form complex polymers with compounds such as fibrinogen or haemoglobin, therefore fibrinogen polymerization is speeded up. Calcium ions (powder form) are used during protein complex fixation on cell membranes, in particular thrombocytes and endotel cells. Higher Ca²⁺ ion concentration stabilises activated Factor V and speeds up Factor XIII activity resulting in fibrinogen network stabilization which is therefore able to create sufficiently organized structure for fibroblast growth and cicatrix formation. During coagulation process Ca²⁺ ions partially participate in thrombocyte adhesion to collagens of exposed wound, and also show partial analgesic effect. This is considered to be due to ion blockage effect on autonomous nerve-endings.



Special features: Haemostatic effect and bactericidal features of the active substance speeds up the healing process. Also, a partial pain relief is observed without the need for local anaesthetics. It is thought to be due to blocking effect of the Ca⁺ ions.

Does it have any negative impact? HEMA LIMIT shows no negative effect. Having stopped the bleeding, HEMA LIMIT is "eliminated" via macrophages acting in healing - histiocytes and neutrophilic granulocytes. Biotransformation is in progress after phagocytizing by tissue macrophages through depolymerisation. Cellulose chains are hydrolytically split by glycosidase into individual monomers glucose, glucuronic acid and cellobiose which are excreted. Degraded HEMA LIMIT products are not detected in plasma nor urine. The preparations are fully absorbed within 12 - 72 hours with no toxicology effect.

Indication: Arresting capillary bleeding and bleeding from parenchymatous organs and resection areas during surgical interventions. It is a perfect alternative to collagen-based haemostats.

Application/Clinical experience: Neurosurgery / General Surgery / Plastic Surgery / Urological Surgery / Gynaecological Surgery / Thoracic / Vascular Surgery / Stomatology / Veterinary

HEMA LIMIT powder^s

HEMA LIMIT powder 3g is an absorbable haemostatic powder destined to stop capillary bleeding and/or venous bleeding from parenchymatous organs, after injury and during or after surgery.

HEMA LIMIT powder

- is in particular destined for professionals in operating theaters to arrest capillary or venous bleeding during or after surgery
- is suitable for use in both ambulances and any areas of surgery or traumatology. It could be also used to arrest bleeding at endoscopy
- shows immediate effect at arresting venous or capillary bleeding from small arteries. The haemostasis is fully achieved by 2-3 minutes after application
- is fully absorbed within 48 to 72 hours, depending on the wound extent
- is entirely eliminated in 21 days, there are no deposits left in tissues and cells
- is hypoallergenic, it exhibits no sensitising properties and causes no adverse immuno-reaction of organism even in case of recurrent application
- is biocompatible, biodegradable and has biostatic features
- is well tolerated by the organism and it encourages wound healing when applied
- is a perfect alternative to collagen haemostats
- no adverse reactions have been reported



HEMA LIMIT matrix

HEMA LIMIT matrix is a sterile haemostatic preparation based on oxidized cellulose available in the flat form with textile structure. It is destined to arrest capillary bleeding and bleeding from parenchymatous organs and resection areas, at surgical interventions.

HEMA LIMIT matrix

- could be applied into cavities (after extirpation of tumours) as well as endoscopy interventions or dental praxis
- the haemostatic effect is almost immediate, the full haemostasis is achieved by 2 minutes after application
- is fully absorbed by 12 - 72 hours, depending on the application form and wound extent
- is entirely eliminated from the body within 21 days, leaving no deposit behind in tissues and cells
- is biocompatible, biodegradable, non-acidifying haemostatic preparation of natural origin
- is hypoallergenic - no sensitive features have been reported, no immunereactions have been initiated, even after repeated application
- is well tolerated by the organism and has a significant effect on healing process in wounds
- no adverse effects as such have been reported
- is an ideal alternative to bovine fibrins and collagens
- the material could be stitched to the tissue if recommended by surgeon

Application/Clinical experience:

Neurosurgery / General Surgery / Plastic Surgery /
Urological Surgery / Gynaecological Surgery / Thoracic /
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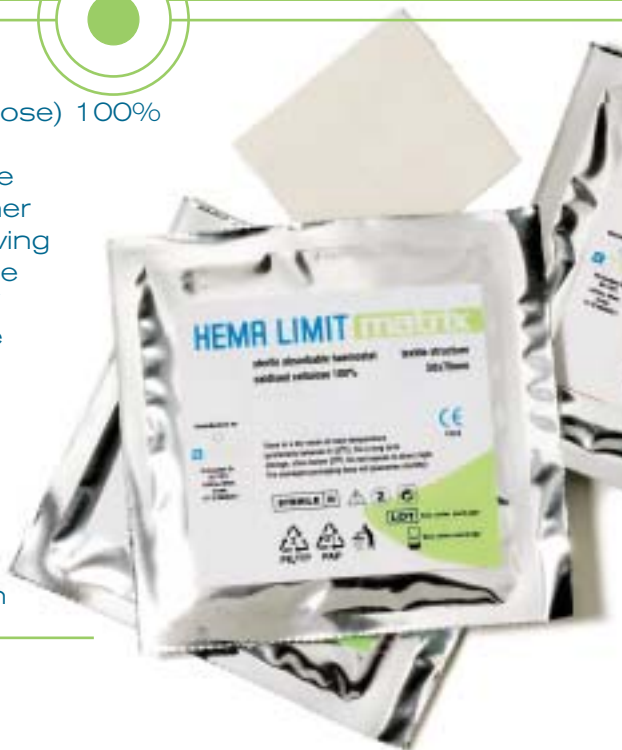
HEMA LIMIT powder^s

- Content:** Carboxycellulosum calcium (calcium salt of oxidized cellulose) 100%
- Packaging:** Plastic bottle with a sprinkler and cover, including an applicator
- Active substance:** Hydrogen calcium salt of oxidized cellulose 3g
- Sterility:** Sterilized by gamma irradiation destined for operating theatres



HEMA LIMIT matrix

- Content:** Carboxycellulosum (oxidized cellulose) 100%
- Packaging:** The material is packed into double sterile packaging. The primary/inner packaging is a silver/black foil having a peel-effect on one side to enable an easy opening. The secondary/outer packaging shall be one-side transparent, with a peel-effect on one side for an easy opening.
- Sterility:** Sterilized by gamma irradiation
- Dimensions provided:**
- | | |
|--------------|--------------|
| 50 x 50 mm | 50 x 70 mm |
| 50 x 100 mm | 50 x 350 mm |
| 100 x 100 mm | 100 x 200 mm |



Produced exclusively for:


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THERAPEUTICS


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