roeko Gelatamp forte

Instructions for use **EN**

PRODUCT DESCRIPTION
Gelatamp forte is a sterile swine gelatin sponge + NaCl (Sodium Chloride), insoluble in water, easy to handle and absorbable that has the purpose of facilitating to stop bleeding. The sponge is whitish in colour and with uniform porosity.

ACTION MECHANISM
Once saturated with blood, the product promotes coagulation serving as a coadjutant in controlling localised bleeding. When used in the correct manner and amount, Gelatamp forte is absorbed within 3-4 weeks. The amount of product to be used and the absorption thereof depend on the extension of the bleeding surface and the type of tissue on which it is applied.

INDICATIONS
Gelatamp forte must be used dry, so as to maximise the absorbent and haemostatic properties, but it can also be soaked with antibiotic or haemostatic solutions. The use in surgical interventions, except for ophthalmic ones, provides for a simple application and, if necessary, a mild compression. The product is conceived to be exclusively used as a haemostatic for controlling venous or arterial capillary bleeding, where other conventional haemostasis procedures (sutures, compression, binding etc) cannot be applied.
Gelatamp forte can be cut to the desired size using sterile scissors without crumbling and it has low adhesiveness with respect to surgical tongs and surgical instruments.

CONTRA-INDICATIONS
- Do not use Gelatamp forte for suturing skin incisions in that it could interfere with the healing and cicatrisation of the skin margins.
- Do not use Gelatamp forte in intravascular cavities due to the risk of emobolisation.
- Do not use Gelatamp forte in embolisation procedures.
- Do not use Gelatamp forte in patients with ascertained allergy against the product.
- Do not use Gelatamp forte on infected wounds.

WARNING
- Use of Gelatamp forte does not authorise to leave out normal haemostasis procedures.
- After reaching haemostasis remove, when possible, the product from the site of application so as to avoid the risk of displacement or compression of the product of other adjacent structures.
- Remove Gelatamp forte from the site of application when used in bone holes, in the spinal cord and/or in the nerve or optic chiasma or in the surrounding or adjacent regions with respect thereto.
- Remove Gelatamp forte from the site of application if used in neurosurgery or in the regions surrounding or adjacent to the nerves given that increasing in volume the product could cause compression damaging, even seriously, the nervous tissue.
- Do not use Gelatamp forte in case of strong arterial bleeding, in case of blood stagnation or stagnation of other organic liquids and when the source of blood is fully occluded.
- Do not use Gelatamp forte in post-partum interventions and for controlling menorrhagia.
- The safety and effectiveness of the Gelatamp forte in ophthalmic interventions was not verified.
- The safety and effectiveness of the Gelatamp forte on children and on pregnant women was not verified.

PRECAUTIONS
- Warning: Gelatamp forte comes sterile and for single use. Unused product fractions must be eliminated. Opened and unutilised packagings must be disposed.
- Warning: When used in closed or narrow tissue spaces it is not recommended to preliminarily compress the product so as to prevent its volume increase, due to contact with organic fluids, from causing damage.
- Warning: Even though it is at times recommended to fill the cavity to obtain haemostasis, Gelatamp forte should not be used in this manner if not after accurately eliminating, after achieving haemostasis, the surplus product.
- Warning: Use Gelatamp forte in the minimum amount to achieve haemostasis and always remove any surplus product from the site of application.
- Warning: Do not use Gelatamp forte alongside autologous blood recovery systems given that it has been proven that particles of haemostatic agents could pass through the transfusion filters of the purification systems
- Warning: Do not use Gelatamp forte together with methyl methacrylate cement. It has been proven that the porous structure weakens the strength of the cement used to fix prosthesis to the bone surface.
- Warning: Cases of incomplete absorption and loss of hearing due to use of haemostatic gelatin sponge in eardrum-plastic operations have been reported.
- Warning: Do not use Gelatamp forte in case of coagulation disorders.
- Warning: Combining Gelatamp forte with pharmacologically active substances or other substances must be carefully evaluated by the surgeon and it is under the surgeon's responsibility in any case.
- Warning: The safety and effectiveness of Gelatamp forte in surgery procedures in urology must be verified. Do not leave Gelatamp forte in renal pelvis, in renal calyces, in the urethra and in the ureter to avoid the potential formation of calculi.
- Warning: it is not recommended to use Gelatamp forte for treating epistaxis given that the product could be inhaled hence causing respiratory complications.
- Warning: literature reveals cases of similar products hence, after carrying out radiography tests, product residues, not fully absorbed, have been confused to tumor diseases.
- Warning: Gelatamp forte can cause fever.

HOW TO USE
- Carefully use these use instructions before using the product.
- Check the wholeness of the packaging before use. The sterility is guaranteed only if the packaging is not damaged or wet.
- Always take asepsis safety measures in all product handling stages.
- Always use the minimum amount of product to reach haemostasis.
- Gelatamp forte can be used as it is dry or soaked with medicine solution.
- Apply the product on the bleeding area by pressing slightly up to achieving haemostasis.
- If the product cannot be removed with haemostasis completed, carefully eliminate the surplus product.
- Use the product by the expiration date indicated on the primary packaging, secondary packaging and on the box.
- The product comes in the formats indicated in the present IFU.

PRESERVATION
Store Gelatamp forte at room temperature and in a dry place. Store Gelatamp forte away from direct sunlight.

Should you observe effects not described in the present illustration leaflet, please report promptly by writing to the following email address: complaint@masciabrunelli.it

	Read the instructions leaflet
	Preserve away from direct sunlight
	Single use only
CE 0483	CE Marking and the identificacion number of the notifying body
	Manufacturer data
LOT	Batch Code
MD	Medical Device
	Date of manufacture
	Use by year/month
	Maximum storage temperature
STERILE R	Sterile. Sterilised with ionising radiation
REF	Reference Number
	Preserve in a dry place
	Do not re-sterilise
	Do not use if packaging is damaged
	Contains biological material of animal origin
	Warning read the use instructions

Gelatamp forte, 10×10×4 mm, REF 60036568

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