



EUROSWISS S.A.

Estuche de origen de axiostat x 10 unidades (5cm x 5cm)



## non-absorbable hemostatic dressing

### Description:

The Axiostat Patch is a sterile, single use, non-absorbable hemostatic dressing. It is composed of Chitosan, a well-known natural polysaccharide generally derived from shellfish which has widely recognized hemostatic properties. The hemostatic dressing can be removed after the clotting has occurred but should not remain on for more than 24 hours. The hemostatic dressing is not intended to be implanted.

### Composition:

Axiostat Patch is made up of chitosan extracted from shellfish. Natural material tends to change color. Hemostatic effectiveness remains unchanged.

### Actions:

When applied with pressure, Axiostat Patch creates a mechanical barrier against bleeding.

### Indications:

The Axiostat Patch is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing for patients and for the rapid control of moderate to severe bleeding. The dressing is indicated for the following wounds: lacerations, abrasions, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

### Warnings:

- Remove within 24 hours.
- It is a non-absorbable hemostatic dressing. Do not implant.
- Do not use if patient is allergic to shellfish.
- Do not use if package is damaged or contents are wet.
- For single use only. Do not re-use or re-sterilize.
- Axiostat Patch when used in vascular procedures, must be under the supervision of a trained healthcare professional. Observe sterile techniques at all times

when using Axiostat Patch in vascular application. Recommend sterile gauze usage to apply uniform pressure and to hold Axiostat Patch in position during vascular procedures.

- After bleeding is controlled, do not remove Axiostat Patch immediately. Keep in position for at least 10 minutes.
- Axiostat Patch is intended for temporary control of bleeding only.

### Precautions:

Employ appropriate groin management post procedure and post hospital discharge to prevent infection when Axiostat Patch is used during vascular procedures.

Notify physician if any of the following occur:

- Bleeding or significant drainage from the puncture site.
- Swelling, redness or warmth around the puncture site.
- Increased tenderness, numbness or cold sensation around the puncture site.

The safety and effectiveness of the Axiostat Patch has not been evaluated in the following patient populations:

- Patients with uncontrolled hypertension (>180 mm Hg systolic).
- Patients with bleeding disorders such as Thrombocytopenia (<100,000 platelet count), thrombasthenia, von Wille Brand's disease, or anaemia (Hgb<10 mg/dl, Het<30).
- Patients receiving glycoprotein IIb/IIIa inhibitors before, during, or after the catheterization procedure.
- Patients with bleeding diathesis or coagulopathy.
- Patients already having hematoma/pseudoaneurysm.
- Patients having ACT (Activated Clotting Time) >180 sec.
- Patients undergoing therapeutic thrombolysis.

### Storage:

Store at ambient temperature. Avoid direct sunlight, heat and moisture.

Distributed in the US by Merit Medical.



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**Hoja Adicional de Firmas**  
**Anexo**

**Número:**

**Referencia:** EURO SWISS S.A.

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