

INSTRUCTIONS FOR USE of medical device

Sterile absorbent hemostatic agent REVUL®

Description

REVUL® is a highly effective hemostatic agent based on a high-molecular natural polymer. A yellow or yellow-white slightly hygroscopic fine powder, odorless. REVUL® is a sterile hemostatic powder for external use.

Contents of packaging

Performance 14, 30 g per bag.

Composition: powder 10 g contains:

Locust bean gum.....	9.6 g
Calcium gluconate	0.4 g

Indications

REVUL® is intended to stop external bleeding of varying intensity, including when large venous and arterial vessels are damaged, mostly at the pre-hospital stage. REVUL® can be used in clinical, field settings and in everyday life.

Mechanism of action

When the powder interacts with blood, REVUL®, due to the large molecular weight of molecules saturated with hydroxyl groups, forms hydrogen bonds with water (which makes up 90–95 % of blood), resulting in aggregation of blood corpuscles and clotting factors at the site of contact, followed by the formation of a blood clot.

Contraindications

Hypersensitivity to the components of the device.

Posology and method of administration

1. Before using REVUL®, clean the wound of foreign matter and blood clots to ensure maximum contact of the powder with the damaged vessel. REVUL® is applied by pouring the powder directly to the source of bleeding.
2. Check the shelf-life and packaging integrity of the medical device.
3. Pat the wound dry with a bandage or any other available material.
4. Open the bag.
5. Fill the wound with the contents of the bag. **DO NOT THROW AWAY THE EMPTY BAG!**
6. Press a bandage or gauze sponge tightly to the wound for 5 minutes. If the bleeding persists, hold for another 5 minutes.

Note: in case of heavy bleeding, tamp the powder into the wound in any available way to avoid leaching the powder by the blood flow.

If the wound is large and one bag is not enough to fill it, take another bag.

7. Apply a pressure bandage to the wound.
8. Transport the victim to the nearest first-aid-station as soon as possible.
9. Pass the empty bag to healthcare professionals.
10. Do not use any remaining powder.

Information for healthcare professionals

1. Clean the wound thoroughly.
2. Remove the product residues from the wound thoroughly washing the wound with a warm 0.9 % sodium chloride solution until blood clots, product residues and other foreign matter are completely removed.
3. Treat the wound according to standard approved clinical protocols.

Adverse reactions

Hypersensitivity reactions.

Warnings and precautions for use

Open REVUL[®] packaging immediately before use; do not reuse.

Do not use expired product.

Do not use the product if the primary packaging is damaged.

For external use only. Avoid contact with the respiratory tract and eyes. In case of contact with eyes, rinse immediately with plenty of water.

Shelf life: 3 years.

Storage conditions

Keep out of reach of children at +5 °C to +30 °C.

Name and address of manufacturer

Yuria-pharm LLC, 10, M. Amosova Str., Kyiv, Ukraine, 03038.

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Manufacturing site address: 21/13, Chygyrynska Str., Cherkasy, Ukraine, 18030.

Graphical symbols and their interpretation	
	Conformity mark to the Technical regulations for medical devices and the code of the conformity assessment body
	Sterile. Sterilized using irradiation
	Do not re-use
	Manufacturer
	Do not use if package is damaged
	Humidity limitation
	Temperature limit

	Caution
	Consult instructions for use
	Date of manufacture
	Use-by date
	Batch code

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