INSTRUCTION for use of medical device

Sterile absorbing hemostatic agent REVUL® performance No. 14

Description

REVUL® performance No. 14, is a highly effective blood stopping agent on the basis of a naturally occurring high molecular weight polymer. It is a slightly hygroscopic, fine powder of yellow or yellow-white color, without odor. REVUL® performance No. 14, is a sterile hemostatic powder for external use.

Content of packaging

Powder in bags of 20 g, 30 g, 40 g, 50 g, 60 g.

Composition of REVUL® performance No. 14:

10 g of powder contain: Locust bean gum – 9.6 g; Calcium gluconate – 0.4 g.

Indications for use

REVUL® performance No. 14, is designed to stop external bleeding of varying intensity, including cases of damage of large venous and arterial vessels, mainly during the pre-hospital phase. REVUL® performance No. 14, can be used in clinical and field environment and in everyday life.

Mechanism of action

When interacting with the blood, due to high molecular weight of molecules that are saturated with hydroxyl groups, REVUL® performance No. 14, forms hydrogen bonds with water (makes up 90-95% of the blood), which leads to aggregation of formed elements of blood and coagulation factors at the site of contact with subsequent formation of a blood clot.

Contraindications

Hypersensitivity to components of the product.

Route of administration and doses

Before using REVUL® performance No. 14, remove foreign bodies, blood clots from the wound to ensure maximum contact of the powder with the damaged vessel. REVUL® performance No. 14, is used by direct filling of the bleeding source with the powder.

Sponge the wound with a bandage or another available material.

Fill the wound with contents of the package. HOLD ON TO THE EMPTY PACKAGE!

Press firmly the bandage or the gauze swab to the wound for 5 minutes. If the bleeding does not stop, keep the bandage or the gauze swab for another 5 minutes.

Note. In case of severe bleeding, tamp the powder into the wound by any means available to avoid washing-out of the powder by the stream of blood.

If the wound is large and one bag is insufficient to fill the wound, use one more bag.

Apply tight dressing to the wound.

Take the victim to the nearest first aid station as soon as possible.

Give the empty bag to the medical personnel.

Do not use the remains of the powder.

Information for medical personnel

- 1. Debride the wound thoroughly.
- 2. Remove the remains of the product from the wound by thoroughly bathing the wound with warm 0.9% sodium chloride solution until complete removal of blood clots, remains of the product and other foreign bodies.
- 3. Debride the wound according to the approved standard clinical protocols.

Adverse reactions

Allergic reactions.

Precautions for use

Open package of REVUL® performance No. 14, directly before the use; the product is designed for single use only.

Before you use the product, check its shelf life and integrity of the package. If the primary package is damaged, do not use the product!

The product is intended for external use only. Prevent contact with airways and eyes. In case of contact with eyes, rinse immediately with plenty of water. Keep out of the reach of children.

Shelf life: 3 years.



How to store

Keep out of the reach of children. Store at a temperature ranging from +5 °C to +30 °C.

Name and address of manufacturer

Yuria-Pharm Ltd., 10, M. Amosova Str., Kyiv, 03038, Ukraine Tel: +38 (044) 275-92-42; +38 (044) 275-01-08

Manufacturing address

21, Chygyrynska Str., Cherkasy, 18030, Ukraine www.uf.ua

www.revul.com.ua

Graphical symbols and their interpretation	
UA.TR.039	THE SYMBOL OF CONFORMANCE TO REGULATION ON MEDICAL DEVICES AND CODE OF THE CONFORMITY ASSESSMENT BODY
STERILE R	THE SYMBOL OF METHOD OF STERILIZATION, DURING WHICH STEAM IS USED
	DO NOT RE-USE
	MANUFACTURE
	DO NOT USE IF PACKAGE IS DAMAGED
+5 °C	TEMPERATURE LIMIT
<u> </u>	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
Ţ <u>i</u>	CONSULT INSTRUCTION FOR USE
M	DATE OF MANUFACTURE

\subseteq	USE-BY DATE
LOT	BATCH CODE

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