ANKAFERD BLOOD STOPPER ABSORBABLE WET TAMPON

This instructions for use (TSD.04-B 07. 01.03) is issued on 15.03.2023 following are view.

• Read this INSTRUCTIONS FOR USE carefully before using Ankaferd Blood Stopper Absorbable Wet Tampon , since it contains important information for the user.
• Keep the instructions for use. You may need to re-read later.
• Consult a healtcare professional for any issue with regard to the user manual or the product, which you did not understand.
• In case of critical bleeding, make sure to apply to a health instiution after using Ankaferd Blood Stopper Absorbable Wet Tampon. During the application, state you stopped the bleeding by using Ankaferd Blood Stopper Absorbable Wet Tampon.
• For the correct use of Ankaferd Blood Stopper Absorbable Wet Tampon, make sure to comply with the use of instruction specified in the present manual.

BOX CONTENT

Each box contains 1 sterile, packaged, single use Ankaferd Blood Stopper Absorbable Wet Tampon Set which contains sterile, packaged, single use Ankaferd Solution inside needle free injector and body absorbable Oxidized Regenerated Cellulose Tampon.
The amount of ABS Solution (ml) inside needle free injector and size of corresponding Oxidized Regenerated Cellulose for five different available products are as follows:

Amount of ABS Solution in needle free Injector	ORC Tampon Size
0,5 ml	(1cm x 2,5cm)
1 ml	(2cm x 2,5cm)
2,5 ml	(2,5cm x 5cm)
5 ml	(5cm x 5cm)
10 ml	(5cm x 10cm)

INTENDED USE AND SUGGESTED AREA OF USE

Ankaferd Blood Stopper Absorbable Wet Tampon is used to stop internal bleedings, traumatic hemorrhages, dental bleedings, sudden bleedings, surgical bleedings, intensive bleedings, bleedings after surgery, endoscopic and laparoscopic procedures, capillary hemorrhages, leakages, capillary, venous and arterial hemorrhages when the tampon is pressed lightly on the cut or on the wound for a short period of time. Ankaferd Blood Stopper Absorbable Wet Tampon must not be placed in the vein or circulatory system.
It is used to stop bleeding when conventional methods are not feasible. The Oxidized Regenerated Cellulose Tampon can be fixed to the tissue with suture if required by the doctor. Ankaferd Blood Stopper Absorbable Wet Tampon is start to be absorbed in the body within 7-14 days, completely disappears in 40 days. Ankaferd Blood Stopper Absorbable Wet Tampon may be used safely in all patient groups. It may be used safely under physician's supervision for pregnant women, children, elderly, hemophiliacs, diabetics and hypertension patients. It is also suitable for endoscopic and laparoscopic use by healthcare professionals.
The use of different sizes of tampon could be required, depending on the size of the wound or the cut, intensity of the bleeding vein, and state of patient's vital functions. Consult the nearest healthcare professional to choose the size of tampon for different type of wounds, before use of it.

WHAT IS OXIDIZED REGENERATED CELLULOSE ?

100 % Oxidized Regenerated Cellulose,absorbable in the body, sterile. It has the advantage of being able to sew in the field.It is a white-yellowish color.It has bactericidal and bacteriostatic effect because of its carboxyl groups (16-24 %).

PHARMACOLOGICAL PROPERTIES

Ankaferd Solution blood stopper, creates a specific erythrocte-protein network, which orients hemostasis physiologically in a short period of time within the plasma and serum.The blood stopping procedure is basically conducted through the above mentioned tissue regenerating network. Ankaferd Blood Stopper Absorbable Wet Tampon stops the bleeding in both individuals with normal hemostatic values and in patients suffering from hemorrhagic diathesis with first and second degree hemostasis disorder, such as hemophiliacs. Its bactericial and fungucidal effects were demonstrated with in vito studies.

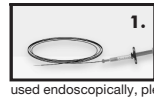
MANUFACTURER: İmmun Gıda İlaç Kozmetik San. ve Tic. Ltd. Şti.
Kireçburnu Cad. Raifbey Sok. No: 8/B Kireçburnu Sarıyer/İSTANBUL
BULK SOLUTION PLACE OF MANUFACTURING: Bikar İlaç San. ve Tic. Ltd. Şti.
Güllü Bağlar Mah. Ankara Cad. Şirin Sok. No:14
Kurtköy/Pendik/İSTANBUL/TÜRKİYE
PLACE OF MANUFACTURING, FILLING, AND PACKAGING:
İmmun Gıda İlaç Kozmetik San. ve Tic. Ltd. Şti. Ferhatpaşa Mah. Yeditepe Cad.
14.Sokak. No:11/13 Ataşehir / İstanbul / TÜRKİYE

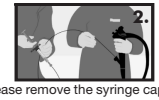
INSTRUCTIONS FOR USE

External use

• The product is ready for use. It does not require special preparation before application.
•Open the Oxidized Regenerated Cellulose Tampon packaging. Spray the Ankaferd solution inside the injector evenly all over the tampon or spray Ankaferd Solution inside the injector to the bleeding area.
• Press Lightly the cellulosic tampon on the bleeding zone allow the Ankaferd Solution to reach to source of bleeding. Although Oxidized Regenerated Cellulose can be left in place if needed, it is recommended to be removed after hemostasis has been achieved. Ankaferd Blood Stopper Absorbable Wet Tampon starts to be absorbed by the body within 7-14 days and completely disappears within 40 days.
• If bleeding can not be stopped despite proper use of Ankaferd Blood Stopper Absorbable Wet Tampon,consult other methods immediately. Apply to the nearest healtcare institution after bleeding stops, and state you used Ankaferd Blood Stopper Absorbable Wet Tampon to stop the bleeding.

Endoscopic & Laparoscopic Usage





• Ankaferd Solution injectors are compatible with the catheter. It can be combined with endoscopic and laparoscopic devices.
• If the Ankaferd Blood Stopper is to be used endoscopically, please remove the syringe cap and lock the syringe to a spray catheter placed inside the endoscope working channel to spray the Ankaferd Blood Stopper on the bleeding point.
•Ankaferd Blood Stopper is made available in five syringe volume options. Select the appropriate variant relevant to the endoscopic or laparoscopic procedure to be completed.
• The spray catheter should be as close as possible to the bleeding point.
• Give sufficient time for hemostasis to happen before applying more. Hemostasis should be happening when a color change is visible.
• If necessary, repeat the application of Ankaferd Blood Stopper several times until hemostasis is achieved.

SIDE EFFECTS

Ankaferd Blood Stopper Absorbable Wet Tampon does not have any reported side effect. Nevertheless, as a natural consequence of the blood contact of its intense iron content, Ankaferd Blood Stopper Absorbable Wet Tampon changes the tissue color of its place of application temporarily. Consult your doctor or a healtcare professional if in doubt, or if an unexpected effect occurs.State the doubt or unexpected effect to 911@immun.com.tr via e-mail.

DRUG INTERACTIONS AND OTHER INTERACTIONS

Ankaferd Blood Stopper Absorbable Wet Tampon does not have any reported drug cross-interaction.It is hypoallergenic.
It does not contain any human blood deriavetes, animal tissue, chemical product and alcohol.

STERILIZATION, USE AND STORAGE CONDITIONS

• The product has been sterilized through the gamma radiation method.
• Keep in a dry place, away from direct sunlight, where the temperature is between 0 and 25 °C.
•The shelf life of the products is 4 years.

WARNING

•Make sure to read the instructions of use before.
•Apply other methods immediately if the bleeding is not be stopped with Ankaferd Blood Stopper Absorbable Wet Tampon.
•Do not use the product in case the package is damaged.
•Each injector and Oxidized Regenerated Cellulose tampon are single use. If used product is used again ABS Absorbable Wet Tampon may not display the proper performance and there is a risk of blood-borne disease transmission in case of using it by different people as well.
•Keep it in places and in the package where children cannot reach.
•Although Oxidized Regenerated Cellulose can be left in place if needed, it is recommended to be removed after hemostasis has been achieved.
•Ankaferd Blood Stopper Absorbable Wet Tampon must not be injected. It must not be placed in the vein or circulatory system.

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