הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 3102.50)

תאריך 25.08.2013

שם תכשיר באנגלית ומספר הרישום EVICEL Human Surgical Sealant 118

61 298 95 02

שם בעל הרישום Omrix Biopharmaceuticals Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
NA	**NA**	**Indication**
4.3 Contraindications: -EVICEL® must not be applied intravascularly. -Hypersensitivity to the active substances or any of the excipients. -Spray application of EVICEL should not be used in endoscopic (intraluminal) procedures where the minimum specified distance from the applicator tip to the target site cannot be assured.	**4.3 Contraindications:** -EVICEL® must not be applied intravascularly. -Hypersensitivity to the active substances or any of the excipients.	**Contraindications**
4.2 Posology and Method of Administration: The use of EVICEL® is restricted to experienced surgeons who have been trained in the use of EVICEL. **4.2.2 Method and route of administration:** For epilesional use. To mitigate the risk of potentially life threatening air embolism EVICEL® should be sprayed using pressurised CO_2 gas only. Prior to applying EVICEL®, the surface area of the wound should be dried by standard techniques (e.g. intermittent application of compresses, swabs, use of suction devices).	**4.2 Posology and Method of Administration:** The use of EVICEL® is restricted to experienced surgeons. **4.2.2 Method and route of administration:** For epilesional use. Prepare the solutions as described in Section 6.6. Before application, the surface of the wound should be as dry as possible. See 6.6 for more detailed instructions.	**Posology, dosage & administration**

The product should only be reconstituted and administered according to the instructions and with the devices recommended for this product. See Sections 4.4 and 6.6 for specific spray recommendations on the required pressure and distance from tissue per surgical procedure and length of applicator tip.		
4.4 Special Warnings and Precautions for Use: ▪ Life-threatening air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer EVICEL®. This event appears to be related to the use of the spray device at higher than indicated pressures and/or in close proximity to the tissue surface. In order to mitigate the risk of air or gas embolism: -EVICEL® should be sprayed using pressurised CO_2 gas only. -EVICEL® spray application should only be used if it is possible to accurately judge the spray distance, especially during laparoscopy. Spray distance from tissue and pressure should be within the ranges indicated by the manufacturer (see table in Section 6.6 for pressures and distances). -When spraying EVICEL®, changes in blood pressure, pulse, oxygen saturation and end tidal CO_2 should be monitored because of the possibility of occurrence of air or gas embolism. -When using accessory tips with this product, the instructions for use of the tips should be followed. ▪ EVICEL® should be applied as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process.	**4.4 Special Warnings and Precautions for Use:** Air or gas embolism has occurred with the use of spray devices employing pressure regulators to administer EVICEL®. This event appears to be related to the use of the spray device at higher than recommended pressures and in close proximity to the surface of the tissue. When applying EVICEL® using a spray device, be sure to use the pressure within the pressure range recommended by the spray device manufacturer. In the absence of a specific recommendation avoid using pressure above 1.4-1.7 bars. Do not spray closer than the distance recommended by the spray device manufacturer. In the absence of a specific recommendation avoid spraying closer than 10-15 cm from the surface of the tissue. When spraying EVICEL®, changes in blood pressure, pulse, oxygen saturation and end tidal CO2 should be monitored because of the possibility of occurrence of air or gas embolism.	**Special Warnings and Special Precautions for Use**

NA	**NA**	**Interaction with Other Medicaments and Other Forms of Interaction**
NA	**NA**	**Fertility, pregnancy and Lactation**
4.8 Undesirable effects: Life threatening air or gas embolism has occurred with the use of spray devices employing pressure regulator to administer EVICEL®. This event appears to be related to the use of the spray device at higher than indicated pressures and/or in close proximity to the tissue surface.	**4.8 Undesirable effects:** A post marketing fatality was reported in association with the use of EVICEL® when applied using a spray device. The case involved an attempt to stop active bleeding by applying EVICEL® using a spray device attached to a wall unit at a higher than recommended pressure for the spray device. In addition, the spray head was placed at a distance from the bleeding site that was closer than the recommended distance guidelines for the application of the sealant. The patient suffered a fatal air embolism.	**Adverse events**
6.6 Instructions for Use, Handling and Disposal: **<u>Preparation</u>** EVICEL® should only be applied using the CE-marked EVICEL® application device and optional use of accessory tips to the device. Detailed instructions for use of EVICEL® in conjunction with the application device and optional accessory tips are provided with the application device and of the accessory tips. The accessory tips should only be used by qualified persons adequately trained in laparoscopic, laparoscopic assisted or open surgical procedures. **<u>Spray Application</u>** Connect the short tube on the application device to the male luer-lock end of the long gas tube. Connect the female luer lock of the gas tube (with the 0.2 µm bacteriostatic filter) to a pressure regulator. The pressure	**6.6 Instructions for Use, Handling and Disposal:** **<u>Preparation</u>** The application device package contains a specially designed device for applying the product and a tube with 0.2 µm bacteriological filter which is used to supply pressurised gas to the device to aerosolise EVICEL® when applied by spraying. **<u>Spray Application</u>** EVICEL® can be sprayed using pressurized CO2 or compressed air. Connect the short tube on the application device to the male luer-lock end of the long gas	**Other**

regulator should be used in accordance with the manufacturer's instructions.
To mitigate the risk of life-threatening air embolism EVICEL should only be sprayed using pressurised CO_2 (see table below).
When applying EVICEL using a spray device, be sure to use pressures and distances from the tissue within the ranges indicated by the manufacturer:

Surgery	Spray set to be used	Applicator tips to be used	Pressure regulator to be used	Distance from target tissue	Spray pressure
Open surgery	EVICEL Applicator Device	6 cm Yellow Flexible Tip	Omrix Pressure Regulator	10 – 15 cm (4 – 6 inches)	20 – 25 psi/ 1.4 – 1.7 bar
		35 cm Black Rigid Tip			
		45 cm Yellow Flexible Tip			
Laparoscopic procedures		35 cm Black Rigid Tip		4 – 10 cm (1.6 – 4 inches)	15 – 20 psi/ 1.0 – 1.4 bar
		45 cm Yellow Flexible Tip		4 – 10 cm (1.6 – 4 inches)	20 – 25 psi/ 1.4 – 1.7 bar

The product should be sprayed onto the surface of the tissue in short bursts (0.1 – 0.2 ml) to form a thin, even layer. EVICEL® forms a clear film over the area of application.

When spraying EVICEL, changes in blood pressure, pulse, oxygen saturation and end tidal CO_2 should be monitored

tube. Connect the female luer lock of the gas tube (with the bacteriostatic filter) to a pressure regulator capable of delivering 1 to 2 bars pressure. The pressure regulator should be used in accordance with the manufacturer's instructions. Utilize spray pressure that is within the recommended guidelines by the device manufacturer [e.g. a pressure of 1.4 to 1.7 bars (measured by gas flow)].

Ensure that distance between the spray head and the application bed is within the recommended guidelines by the device manufacturer. The distance between the nozzle and the tissue surface should ideally be 10 to 15 cm. The product should then be sprayed onto the surface of the tissue in short bursts (0.1 – 0.2 ml) to form a thin, even layer. EVICEL® forms a clear film over the area of application.

because of the possibility of occurrence of air or gas embolism. When using accessory tips with this product, the instructions for use provided with the tips should be followed.		