

רופא / ה, רוקח / ת ואח / ות נכבד / ה
חברת אומריקס מודיעה על העידכונים הבאים בעלון לרופא של התכשיר

אויסל Evicel Human Surgical Sealant

צורת מינון: Solution

צורת מתן: Topical in Surgery

שם וכמות המרכיבים הפעילים: Human Clottable Protein 50 – 90mg/mL

Human Thrombin 800 – 1200 IU/mL

Calcium Chloride 5.6 – 6.2 mg/mL

התוויה:

General haemostasis:

Evicel is used as supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis.

Efficacy has been demonstrated in liver surgery and orthopaedic surgery.

Evicel is also indicated as suture support for haemostasis for suture line sealing in dura mater closure.

עדכונים בעלון לרופא

ברצוננו להודיע שהעלון לרופא עודכן. בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות **בצהוב** והסרות מידע כטקסט מחוק):

1. עדכון טבלת תופעות לוואי בסעיף: Undesirable effects

Tabulated list of adverse reactions

The table presented below is according to the MedDRA system organ classification (SOC and Preferred Term Level).

Frequencies have been evaluated according to the following convention: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

MedDRA System Organ Class	Preferred Term	Frequency
<i>Adverse reactions in retroperitoneal or intra-abdominal surgery studies</i>		
Infections and infestations	Abdominal abscess	Common
General disorders and administration site conditions	Pyrexia	Common
Blood and lymphatic system disorders	Coagulopathy	Common
<i>Adverse reactions in vascular surgery study</i>		
Infections and infestations	Graft infection, Staphylococcal infection	Uncommon
Vascular disorders	Haematoma	Uncommon
General disorders and administration site conditions	Oedema Peripheral	Uncommon
Investigations	Decreased haemoglobin	Uncommon
Injury, poisoning and procedural complications	Incision site haemorrhage	Uncommon
	Vascular graft occlusion	Uncommon
	Wound	Uncommon
	Post procedural haematoma	Uncommon
	Post-operative wound complication	Uncommon
<i>Adverse reactions in neurosurgery study</i>		
Infections and infestations	Meningitis	Common
Nervous system disorders	Intracranial hypotension (CSF leakage)	Common
	CSF rhinorrhoea	Common
	Headache	Common
	Hydrocephalus	Common
	Subdural hygroma	Common
Vascular disorders	Haematoma	Common

2. עדכון סעיף *Adverse Reaction Rates in Retroperitoneal or Intra-Abdominal Surgery Studies*, ע"י הוספת:

In a study in a paediatric population involving 40 patients (20 patients treated with EVICEL and 20 controls), two adverse events (pyrexia and coagulopathy) were considered possibly related to EVICEL by the investigator.

3. ע"י הוספת: Adverse Reactions - Vascular Surgery עדכון סעיף

A non-interventional post-authorisation safety study was conducted which involved 300 patients undergoing vascular surgery during which EVICEL was used. Safety monitoring focused on the specific adverse reactions of graft patency, thrombotic events, and bleeding events. No adverse reactions were reported during the study.

4. עדכון סעיף Pharmacodynamics Properties, ע"י הוספת:

Paediatric population

Limited paediatric data are available to support efficacy and safety of EVICEL in this population. Of 135 patients undergoing retroperitoneal and intra-abdominal surgery who were included in the controlled study of EVICEL, 4 paediatric patients were treated with EVICEL. Of these, 2 were children aged 2 and 5 years and 2 were adolescents of 16 years. In addition, a paediatric controlled clinical study evaluating the safety and effectiveness of EVICEL as an adjunct to haemostasis in soft tissue or parenchymal organ bleeding was conducted in 40 patients (20 treated with EVICEL and 20 controls). The patients age range was from 11 months to 17 years. Data from this study were consistent with results from the previous study in retroperitoneal and intra-abdominal surgery where non-inferior haemostatic efficacy of EVICEL was demonstrated.

5. עדכון סעיף Shelf life, ע"י הוספת (החלק שהתווסף מסומן בצהוב):

The expiry of the product is indicated on the packaging materials.

After thawing, unopened vials can be stored at 2-8°C and protected from light, for up to 30 days, without being frozen again during this period. The vials can be stored at room temperature for up to 24 hours. By the end of this period the product has to be used or discarded.

6. עדכון סעיף Special Precautions for Storage (החלק שהתווסף מסומן בצהוב):

Store in a freezer at or below -18°C. Do not refreeze.

Keep the vials in the outer carton in order to protect from light.

The vials must be stored in an upright position.

For storage conditions after thawing of the medicinal product, see section 6.3.

The new expiry date at 2-8°C should be noted on the carton but should not exceed the expiry date printed by the manufacturer on the carton and label. At the end of this period the product has to be used or discarded.

Once drawn up into the application device, the product must be used immediately.

7. עדכון סעיף Special Precautions for Disposal and Other Handling ,
 ע"י עדכון הטבלה (תוספות מסומנות בצהוב והסרות מידע כטקסט מחוק):

Surgery	Spray Set to Be Used	Applicator Tips to Be Used	Pressure Regulator to Be Used	Recommended Distance from Target Tissue	Recommended 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		4 – 10 cm (1.6 – 4 inches)		15 – 20 psi/ 1.0 – 1.4 bar	
35 cm Black Rigid Tip					
45 cm Yellow Flexible Tip					20 psi/ 1.4 bar
Laparoscopic procedures					

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

<http://www.health.gov.il>