הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך 24.2.2015

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
EVICEL® is also indicated as suture support for haemostasis for suture line sealing in dura mater closure.	**NR**	**Indication**
• EVICEL® must not be applied intravascularly. • Hypersensitivity to the active substances or any of the excipients listed in section 6.1. • Spray application of EVICEL should not be used in endoscopic procedures. For laparoscopy, see Section 4.4. • EVICEL must not be used for sealing the suture line in dura mater if there are gaps of greater than 2 mm after suturing. • EVICEL must not be used as a glue for the fixation of dural patches. • EVICEL must not be used as a sealant when the dura mater cannot be sutured	• 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 procedures. For laparoscopy, see Section 4.4.	**Contraindications**
….for suture line sealing in dura mater clo doses of up to 8 ml were used….	NR	**Posology, dosage & administration**
…… ▪ Adequate data are not available to support the use of this product in tissue gluing, ~~neurosurgery~~, application through an endoscope for treatment of bleeding or in gastrointestinal anastomoses.	…… ▪ Adequate data are not available to support the use of this product in tissue gluing, neurosurgery, application through an endoscope for treatment of bleeding or in gastrointestinal anastomoses.	**Special Warnings and Special Precautions for Use**

- The concomitant use of EVICEL for dural suture line sealing with implants from synthetic materials or dural patches has not been evaluated in clinical studies.
- The use of EVICEL in patients undergoing radiotherapy within 7 days after surgery has not been evaluated. It is not known whether radiation therapy could affect the efficacy of fibrin sealant when used for suture line sealing in dura mater closure.
- Complete haemostasis should be achieved before application of EVICEL to seal the dural suture line.
- The use of EVICEL as a sealant in transphenoidal and otoneurosurgical procedures has not been studied

6.6 Instructions Special precautions for Use, disposal and other Handling and Disposal

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 35 cm Black Rigid Tip 45 cm Yellow Flexible Tip	Omrix Pressure Regulator	10 – 15 cm (4 – 6 inches)	20 – 25 psi/ 1.4 – 1.7 bar
Laparos		35 cm		4 – 10	15 – 20

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copic procedures		Black Rigid Tip		cm (1.6 – 4 inches)	psi/ 1.0 – 1.4 bar		copic procedures		Black Rigid Tip		cm (1.6 – 4 inches)	psi/ 1.0 – 1.4 bar						
		45 cm Yellow Flexible Tip		4 – 10 cm (1.6 – 4 inches)	20 psi/ 1.4 bar				45 cm Yellow Flexible Tip		4 – 10 cm (1.6 – 4 inches)	20 – 25 psi/ 1.4 – 1.7 bar						
NA							**NA**												**Interaction with Other Medicaments and Other Forms of Interaction**
NA							**NA**												**Fertility, Pregnancy and Lactation**

MedDRA System Organ Class	Preferred Term
Adverse Reactions in Retroperitoneal or Intra-Abdominal Surgery Study	
Infections and infestatic	Abdominal abscess
Adverse Reactions in Vascular Surgery Study	
Infections and infestations	Graft infection, Staphylococcal infectior
Vascular disorders	Haematoma
General disorders and administration site conditions	Oedema peripheral
Investigations	Decreased haemoglobin
Injury, Poisoning and Procedural Complicatio	Incision site haemorrhage Vascular graft occlusion Wound Post procedural haematoma Post-operative wound complication
Adverse Reactions in Neurosurgery Study	
Infections and Infestatic	Meningitis
Nervous System Disorde	Intracranial hypotensior leakage) CSF rhinorrhoea Headache Hydrocephalus Subdural hygroma
Vascular Disorders	Haematoma

Adverse Reactions – Neurosurgery

In a controlled study involving 139 patients undergoing elective neurosurgical procedures (89 treated with EVICEL and 50 controls), a total of 7 subjects treated with EVICEL experienced nine AEs that were considered to be possibly related to the study product. These included

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Adverse events

intracranial hypotension (CSF leakage), CSF rhinorrhea, meningitis, headache, hydrocephalus, subdural hygroma, and haematoma. The incidence of CSF leakage and the incidence of Surgical Site Infections were monitored as safety endpoints in the study. At 30 days post-operatively the incidence of SSIs was similar between the two treatment groups. Post-operative CSF leakage occurred within 30 days from treatment in 4/89 (4.5%) subjects treated with EVICEL (two cases of CSF leakage with impaired wound healing and two cases of rhinorrhoea) and in 1/50 (2.0%) subjects treated with additional sutures. *Reporting of suspected adverse reactions* Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il) or by email (adr@MOH.HEALTH.GOV.IL). Additionally, you may also report to the MAH, Omrix Biopharmaceuticals Ltd. by one of the following 2 ways: Call Omrix switchboard: 03-5316531 Email *:* ra-omrilpv@its.jnj.com		