



פברואר 2023

רופא/ה, רוקח/ת נכבד/ה,

אלופיסל® ; Alofisel®

חברת טקדה מתכבדת להודיעכם כי העלון לרופא של התכשיר שבנדון, התעדכן בינואר 2023. העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות. כמו כן, מצורף לפרסום זה וניתן לקבל העתק מודפס על ידי פניה לבעל הרישום, טקדה ישראל בע"מ בטלפון 03-3733140.

נוסח ההתוויה כפי שאושרה ע"י משרד הבריאות:

Alofisel is indicated for the treatment of complex perianal fistulas in adult patients with non-active/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. Alofisel should be used only after conditioning of the fistulas.

צורת מינון:

Suspension for injection

הרכב וחוזק:

Darvadstrocel 5,000,000 cells/ML

העדכונים העיקריים בעלון לרופא הינם (טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן כטקסט אדום עם קו חוצה):

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4.4. Special warnings and precautions for use

Traceability

~~In order to improve~~ The traceability requirements of biological-cell-based therapy medicinal products, must apply. To ensure traceability the name and the batch number of the administered Product, the batch number and the name of the treated patient should must be clearly recorded. kept for a period of 30 years after the expiry date of the product.

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Blood, organ, tissue and cell donation

Patients treated with Alofisel must not donate blood, organs, tissues and cells for transplantation.

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Takeda Israel Ltd.

25 Efal st., P.O.B 4140, Petach-Tikva 4951125
Tel:+972-3-3733140 Fax : +972-3-3733150



4.6 Fertility, pregnancy and lactation

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Breast-feeding

~~As a precautionary measure, darvadstrocel is not recommended for administration during breast-feeding. It is unknown whether darvadstrocel is excreted in human milk. A risk to the breast-fed infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Alofisel therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.~~

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6.6 Special precautions for disposal and other handling

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Precautions to be taken for the disposal of the medicinal product

~~Any unused product or waste material should be disposed of in accordance with local requirements.~~ Unused medicinal product and all material that has been in contact with Alofisel (solid and liquid waste) must be handled and disposed of as potentially infectious waste in accordance with local guidelines on handling human-derived material.

בברכה,
טלי סרי
רוקחת ממונה
טקדה ישראל בע"מ