October 2023

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הנדון: אלופיסל® Alofisel

חברת טקדה ישראל בע"מ מתכבדת להודיעכם על עדכון בעלון לרופא של התכשיר שבנדון.

נוסח ההתוויה כפי שאושרה ע"י משרד הבריאות:

Alofisel is indicated for the treatment of complex perianal fistulas in adult patients with nonactive/ 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.

מרכיב פעיל: Darvadstrocel 5,000,000 cells/ML

צורת מינון: Suspension for injection

להלן העדכונים העיקריים בעלון לרופא (טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן כטקסט ~~אדום עם קו חוצה~~, טקסט המהווה החמרה מודגש בצהוב) אך קיימים עדכונים נוספים :

4.8 Undesirable effects

Summary of the safety profile

Based on clinical trial and post-marketing data, The most commonly reported ~~common treatment-emergent~~ adverse drug reactions ~~events~~ were anal abscess, ~~(Alofisel: 19.4% patients; control group: 13.7% patients)~~, proctalgia ~~(Alofisel: 14.6% patients; control group: 11.8% patients)~~ and anal fistula with the most commonly reported serious adverse drug reactions of anal abscess and anal fistula.~~(Alofisel: 10.7% patients; control group: 7.8% patients).~~

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Table 1. Adverse reactions

System Organ Class	Frequency	Adverse Reactions
Infections and infestations	Common	Anal abscess*
Gastrointestinal disorders	Common	Proctalgia*,†
	Common	Anal fistula*
Injuring, poisoning and procedural complications	Common	Procedural pain†*

*Also seen in post-marketing experience

†*Conditioning reactions occurring up to seven days after the fistula preparation for treatment administration.

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Description of selected adverse reactions

The following adverse reactions were identified in the multicentre, pivotal clinical trial ADMIRE-CD.

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Anal abscess

Up to week 52, 20 (19.4%) and 14 (13.7%) patients developed 21 and 19 anal abscesses in the Alofisel and control groups, respectively, of which 4 and 5 anal abscesses in respective groups (3.9% patients in both groups) were of severe intensity. Treatment-related anal abscess were reported in 8 (7.8%) and 9 (8.8%) patients in the Alofisel and control groups, respectively. Up to week 104, 15 (14.6%) and 8 (7.8%) patients developed 15 and 9 serious anal abscesses in the Alofisel and control groups, respectively.

Proctalgia

Up to week 52, 15 (14.6%) and 12 (11.8%) patients developed 20 and 17 proctalgia in the Alofisel and control groups, respectively, none of these proctalgia being serious in any group up to week 104. Treatment-related proctalgia were reported in 5 (4.9%) and 8 (7.8%) patients in the Alofisel and control groups, respectively. There were no patients in Alofisel group with proctalgia of severe intensity and 3.9% patients with 4 proctalgia in the control group.

Anal fistula

Up to week 52, 11 (10.7%) and 8 (7.8%) patients developed 12 and 8 anal fistulas in the Alofisel and control groups, respectively, none of these being of severe intensity. Treatment-related anal fistula were reported in 3 (2.9%) and 3 (2.9%) patients in the Alofisel and control groups, respectively. Up to week 104, 5 (4.9%) and one (<1.0%) patients developed 5 and 1 serious anal fistulas in the Alofisel and control groups, respectively.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.

כמו כן, מצורף לפרסום זה וניתן לקבל העתק מודפס באמצעות פנייה לבעל הרישום:

טקדה ישראל בע"מ, טל': 03-3733140.

בברכה,

טלי סרי

רוקחת ממונה

טקדה ישראל בע"מ

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