Alofisel®

(darvadstrocel)

Mode of administration

[GUIDE for SURGEONS]

Healthcare professionals are asked to report any suspected adverse reactions, including medication errors, via HPRA

- Online form: https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form
- By downloading a copy of adverse reaction report form (Word version). or e-mail completed forms to medsafety@hpra.ie
- By printing our adverse reaction report form (Word version) and posting a completed copy to the HPRA by freepost.
- By calling on (01) 676 4971.

Adverse Events and Product Complaints should also be reported to Takeda Products Ireland Ltd - 1800 937 970 (freephone from Ireland only) or +44 (0)3333 000181 or by e-mail: AE.GBR-IRL@takeda.com

Version 2.0 – Approved 03/2024

ALOFISEL® (DARVADSTROCEL)

- ALOFISEL® (darvadstrocel) is a suspension of expanded human adipose stem cells, indicated for the treatment of complex perianal fistulae in adult patients with non-active/mildly active luminal Crohn's disease, when fistulae have shown an inadequate response to at least one conventional or biologic therapy.
- Before scheduling Alofisel administration, the surgeon must characterise the fistula, ensuring that no abscesses are present and that local mucosal disease is mild or inactive. In case of an abscess, incision and drainage are needed, and setons should be placed, if appropriate, in accordance with routine surgical procedures.
- Following fistula conditioning, ALOFISEL® (darvadstrocel) is injected locally in the fistula region in a surgical environment, under regional or general anesthesia.
- A single dose of ALOFISEL® (darvadstrocel) consists of 120 million cells. The dose is provided as 4 vials, containing 30 million cells in 6 mL suspension each.

1 dose = 4 vials = 120 million cells

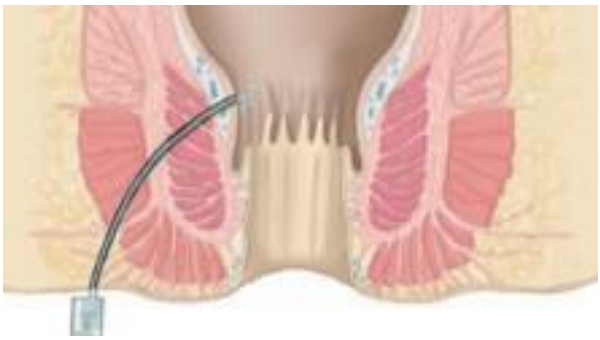
- ALOFISEL® (darvadstrocel) mode of use comprises 2 main steps:
  1. Fistula conditioning.
  2. Product administration (preparation and injection).

FISTULA CONDITIONING

- Prior to injecting ALOFISEL® (darvadstrocel), condition the fistula according to the following steps:

1. If setons are in place, remove them.

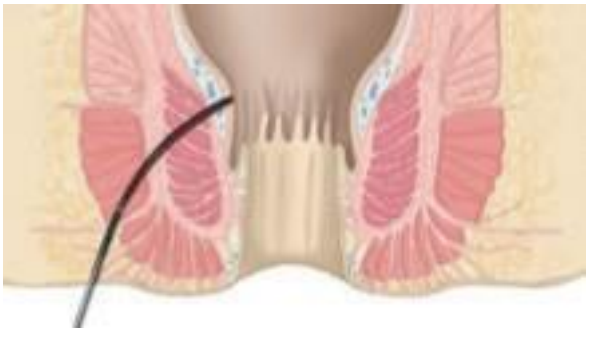
2. Characterise the fistula and identify the location of the internal opening(s). This can be done by injecting saline solution through the external opening(s) until it exits via the internal opening(s).



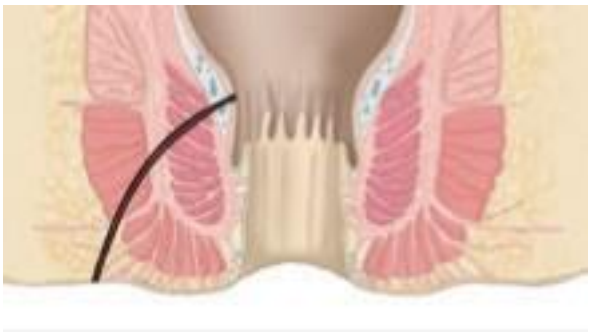
Warning:

Injecting agents other than saline solution (e.g. hydrogen peroxide, methylene blue, iodine solutions or hypertonic glucose) is not allowed, as they compromise the viability of the cells to be injected.

3. Vigorously scrape all fistula tracts using a metallic curette with particular emphasis on the internal opening(s) area(s).



4. Close the internal opening(s) with an absorbable suture through the anal canal.



PRODUCT PREPARATION AND INJECTION

PREPARATION

- Resuspend ALOFISEL® (darvadstrocel) vials by gently tapping the bottom of the vials until a homogeneous suspension is obtained, avoiding bubble formation. ALOFISEL® (darvadstrocel) must be injected immediately after resuspension to prevent cell re-sedimentation.

- To extract the contents of each vial, remove the green plastic cap to access the rubber seal, place the vial upside down, and gently aspirate all contents using a syringe with a conventional needle no thinner than 22G.

- In order to reach the internal opening(s), replace the aspiration needle by a longer needle, also no thinner than 22G. A needle for spinal injection of about 90 mm length is appropriate for this purpose.

Warning:

Thinner needles can cause cell disruption during injection, compromising the efficacy of treatment.

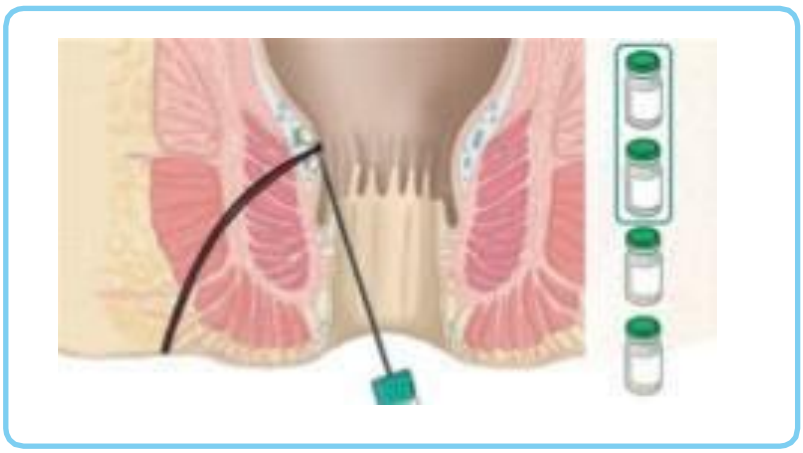
ALOFISEL® (DARVADSTROCEL)

INJECTION

- Inject ALOFISEL® (darvadstrocel) in the following way:

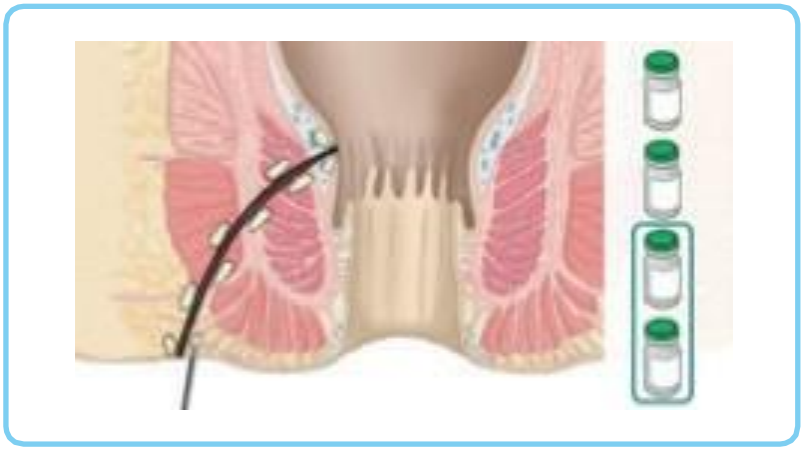
1. Introduce the needle via the anus and inject the contents of 2 vials into the tissue surrounding the internal opening. Make several small blebs to deposit the cell suspension.

   If more than one internal opening exists, distribute the contents of the 2 vials evenly into the tissue around both internal openings.



2. Introduce the needle via the external opening and inject the contents of the remaining 2 vials superficially into the tissue walls along the length of the fistula tracts, again making several small blebs. Ensure that the product is not injected into the lumen of the fistula tracts in order to avoid the leakage of cells.

   In the case where more than one tract is treated, the contents of the 2 vials should be distributed equally across all tracts.



Warning:

Ensure that the product is not injected into the lumen of the fistula tracts in order to avoid the leakage of cells.

- Softly massage the area around the external opening(s) for 20 to 30 seconds and cover the external opening(s) with a dressing.

- Discharge the patient according to the principles of major ambulatory surgery.

MEDICATION ERRORS

An error in the handling or administration of Alofisel, such as those warned against above, may result in a reduction of the dose administered and subsequent reduction in efficacy. In the event of such an error, healthcare professionals are advised to consider the potential impact of loss of dose on the patient's treatment.

In addition to adverse events, healthcare professionals are asked to report medication errors to Takeda on 1800 937 970 or email: AE.GBR-IRL@takeda.com and HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

For further information, please check the Summary of Product Characteristics