Alofisel®

(darvadstrocel)

Receipt and storage instructions

[GUIDE for PHARMACISTS]

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

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ALOFISEL® (DARVADSTROCEL)

- ALOFISEL® 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.
- Following fistula conditioning, ALOFISEL® is injected locally in the fistula region in a surgical environment, under regional or general anesthesia.
- A single dose of ALOFISEL® consists of 120 million cells distributed in 4 vials. Each vial contains 30 million cells in 6 mL of suspension.

1 dose = 4 vials = 120 million cells

- The four glass vials are packed together and placed in a shipment container for transport. A temperature monitoring device is included within the shipment container.
- ALOFISEL® is ready to be used; no manipulation is needed at the hospital apart from resuspension of the cells in the vial just before administration. Resuspension will be carried out by the surgeon.

CONTENTS OF THE SHIPPING CONTAINER

The temperature controlled shipping container should arrive with the following contents:

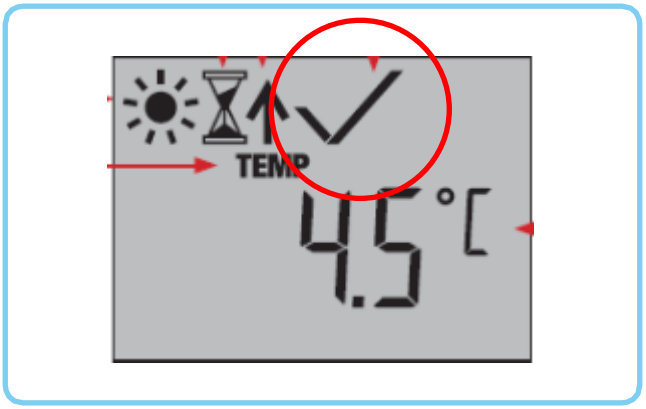
- 4 vials of Alofisel in an outer carton, supported with bubble wrap
- Two temperature monitoring devices
- Product Receipt Control Document
- Certificate of Conformity and Release
- Certificate of Analysis

On the outside of the box will be a plastic pouch containing the transport documents.

PRODUCT RECEIPT AND STORAGE

- The product must be kept at 15°C-25°C at all times until it is administered. Keep the shipment container away from heat and direct light sources, and do not refrigerate or freeze.
- Upon arrival of the courier, visually inspect the shipping container for any excessive sign of damage or tear. Note any observation on the transport documents accompanying the shipment.
- Open the shipping container lid and extract the temperature monitoring device to check that the product has been kept at the required temperature during transport. Close the container lid immediately after, to prevent changes in temperature ranges.
- The temperature monitoring device has to be checked as follows:
  1. Stop the temperature monitoring device by pressing the STOP button for minimum 3 seconds until the Stop icon ● appears in the upper right corner of the screen.

  2. In case there is no temperature alarm and no excursion outside the range (15° – 25°C) a « ✓ » is displayed. The product has been maintained in the adequate temperature range during transport and you may proceed to step 6 i.e. returning the stopped device to the courier and using the product.



3. In case there is a temperature alarm and an excursion outside the range (15° – 25°C) an «X» and an arrow are displayed.

4. In case of an alarm, download the report from the device by connecting it to any PC / MAC. No extra software required. Click on pdf file.

5. Double click on the PDF file to open the report. You will see in the chart any temperature excursion outside the range (15° – 25°C). Send PDF to DL.alofisel.quality@takeda.com and contact Takeda immediately for further instructions. For contact details: please use contact phone numbers delivered by Takeda in Product Receipt Control Document (PRCD).

6. Return the temperature monitoring device to the courier.

- Briefly reopen the shipping container to visually inspect the product for any sign of damage. Assess the batch number, expiry date and time and product characteristics against the accompanying shipping documents and Certificate of Conformance. Close the container immediately after, to prevent changes in temperature ranges. Should there be any discrepancy uncovered within any such step, please contact Takeda immediately and wait for instructions.

- Duly sign all transport documents and note any observation. Return the signed documents and temperature monitoring device to the courier.
- Prior to delivering the shipping container to the operating room, confirm the expiry details against the product label and delivery note (date and hour in Central-European-Time (CET) zone format). In case that expiry date and time is surpassed do not use the product.
- Alofisel® (darvadstrocel) is ready to be used; no manipulation is needed at the Health Care facilities.

For further information, please check the Summary of Product Characteristics