Alofisel®

(darvadstrocel)

Potential microbial contamination

[GUIDE for HEALTHCARE PROFESSIONALS]

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® (darvadstrocel) is a suspension of expanded human adipose stem cells.
- Due to the cellular nature of the product, the manufacture of Alofisel® (darvadstrocel) cannot include terminal sterilisation, purification, viral removal or viral inactivation steps. Therefore, transmission of bacterial, viral, fungal or prion pathogens might potentially occur.
- Risk assessment and a number of specific control measures are applied from donor selection through manufacturing process to reduce the risk of potential transmission of infectious agents by Alofisel® (darvadstrocel).
- Quality control of Alofisel® (darvadstrocel) encompasses testing for sterility, mycoplasma, bacterial endotoxins, endogenous retroviruses and adventitious viruses to detect contamination.

IMPORTANT SAFETY CONSIDERATIONS

Final sterility check

- As the product must be administered within 72 hours of release, the results of the final sterility check, which requires 14 days of incubation, will not be available before administration of the product.
- Patients should be followed up for potential signs of infection after administration.
- If microbial contamination is identified after product release, the healthcare professional will be notified by Takeda immediately by phone and/or email. Therefore, it is important for the manufacturing batch number of the product to be documented in each patient's medical record.
- Takeda will confirm to the treating healthcare professional the microbe identified.
- The treating healthcare professional can then determine the most appropriate treatment for the patient based on the nature of the contamination and the symptoms (if any) which the patient presents with.

Please refer to the full Summary of Product Characteristics for Alofisel® (darvadstrocel) for further information regarding the safety of the product.