

IS IT POSSIBLE TO GET AN INFECTION FROM TREATMENT WITH ALOFISEL®?

Alofisel® is a live cell therapy and, therefore, the final product cannot be sterilized. The medicine is tested at various stages during its manufacture to ensure that it is free of infection. As the final test is performed just before Alofisel® is sent to the hospital, the results of this test are not yet known when you receive the treatment. If the results indicate an infection (this is highly unlikely), your treatment team will be informed and will tell you if you need any laboratory tests or treatment for the infection. If you feel unwell or have a fever following the procedure, please tell your doctor as soon as possible.

It is important to report any suspected side effects. This allows continued monitoring of the medicine's risk-benefit balance. Report any suspected side effect to your doctor.

You can also report side effects to the Ministry of Health using the online form for reporting side effects on the Ministry of Health home page: www.health.gov.il

You can also use this link: <https://sideeffects.health.gov.il>

To report side effects to Takeda Israel Ltd., send an e-mail to AE.ISR@takeda.com or call 03-3733140

This information brochure was developed by Takeda to assist patients receiving Alofisel® (Darvadstrocel). Please talk to your doctor about any questions related to this medicine.

This brochure and its content was approved by the Ministry of Health in May 2023.



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ALOFISEL®
(darvadstrocel)

**PATIENT INFORMATION
BROCHURE**

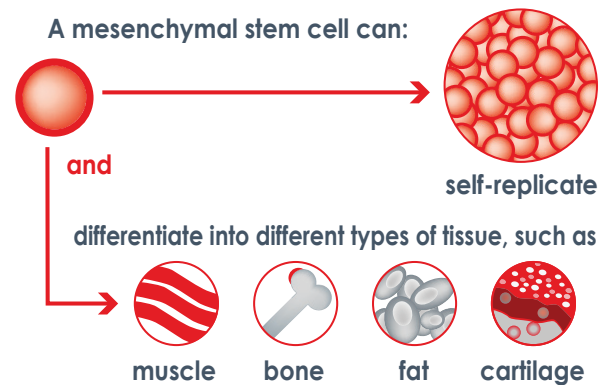
WHAT IS ALOFISEL®?

Alofisel® is a preparation used for the treatment of complex perianal fistulas in adult patients with Crohn's disease, when the other symptoms of the disease are controlled or have a mild intensity. Alofisel® is given when the fistulas have not responded sufficiently well to at least one conventional or biological treatment. Alofisel should be only used after the fistulas have been pre-treated.

Alofisel consists of stem cells which are taken from fat tissue of healthy adult donors (called mesenchymal stem cells) and then grown in a laboratory. Each dose of Alofisel® contains 4 vials with 120 million stem cells. When injected close to the wall of the perianal fistula, Alofisel® can reduce inflammation and increase the likelihood of the fistula healing.

WHAT ARE STEM CELLS AND HOW CAN THEY BE USED TO TREAT PERIANAL FISTULAS?

Alofisel® is a stem cell preparation that was developed specifically to treat perianal fistulas in patients with Crohn's disease. Mesenchymal stem cells are a special type of biological cells present in many types of adult tissues. They can differentiate into many cell types, such as fat cells and bone cells. They can also divide and create additional stem cells. In adult organisms, stem cells replace tissues and constitute an important repair system for the body. The stem cells in Alofisel® are precursors of fat cells that were developed using adult tissues from healthy volunteers.



WHY IS IT IMPORTANT THAT YOU DO NOT MISS YOUR APPOINTMENT?

Preparing Alofisel® is a multi-step process which takes a few weeks. Each dose of Alofisel® is prepared on demand for each individual patient.

If you do not come in for your appointment, the dose that was prepared especially for you cannot be used and the cells will be discarded.

It is important to let your healthcare professionals know of any change in your medical condition as soon as possible before your appointment.

WHAT DO YOU NEED TO REMEMBER BEFORE YOUR TREATMENT?

- Remember the date of your appointment and be sure to arrive on time for your treatment.
- Carefully read the information provided by your doctor and make sure you understand how the treatment will proceed, possible side effects and risks associated with this treatment.
- You are advised to come to your appointment with a companion.

HOW IS THE TREATMENT ADMINISTERED?

Alofisel® is administered by a surgeon experienced in diagnosis and treatment of perianal fistulas.

- The treatment is administered in an operating room under general anesthesia.
- In the first step, the surgeon prepares your fistula for injection. This step includes finding the fistula tract, cleaning the fistula, and identifying the inner and outer openings.
- Alofisel® is injected into the tissue surrounding the fistula tract. Then the outer opening is covered with a sterile bandage.
- After the injection you will have to stay in hospital for monitoring, as instructed by the medical staff according to the standard practice with any procedure conducted under general anesthesia.

DOES ALOFISEL® HAVE ANY SIDE EFFECTS?

Like with all medicines, this medicine may also cause side effects, although not everybody experiences them. Do not be alarmed by this list of side effects; you may not experience any of them.

Some side effects of Alofisel® treatment which were reported in clinical trials are related to the process of cleaning your fistulas. In general, these side effects are mild and most of them disappear in the days following the fistula treatment procedure.

Common side effects:

- Anal abscess
- Development of new anal fistula or relapse of treated fistula
- Proctalgia (pain in the rectum or anus)
- Procedural pain (pain after fistula cleaning)

In addition to the side effects listed above, there is a possibility that ectopic tissue (tissue that grows outside of its natural place) may develop.

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

