



Medicine: darvadstrocel (brand name: Alofisel®) for the treatment of complex perianal fistulas in adults with Crohn's disease

Takeda UK Ltd

What is darvadstrocel used for?

Darvadstrocel is used to treat complex perianal fistulas in adults with Crohn's disease (a chronic inflammatory bowel disease). Perianal fistulas are abnormal channels that develop between the end of the bowel and the skin around the anus. The channels may become filled with pus and may cause severe pain and irritation. Complex fistulas can have several channels and openings which branch off the channels. Darvadstrocel is used to treat complex fistulas when other medicines have not worked well enough, in patients whose symptoms of Crohn's disease are mild or well controlled.

How does darvadstrocel work?

Darvadstrocel is a type of medicine called a somatic cell therapy product. It uses stem cells from the fat tissue of a healthy adult donor, which are grown in the laboratory to increase their number. They are then injected into the patient's fistula where they help to reduce inflammation and grow new tissue. This helps the fistula heal and close.

What has SMC said?

SMC has not recommended darvadstrocel for the treatment of complex perianal fistulas in patients with Crohn's disease as described above.



Why has SMC said this?

SMC looks at how well new medicines work compared with current treatments available in Scotland and in relation to how much they will cost to buy and administer (for example, if the medicine has to be given at a clinic or side effects have to be monitored).

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland. When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not just those who may be treated with the medicine under consideration.

To do this SMC consider the following:

- Clinical trial and economic evidence from the company that makes the medicine.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.
- Information from patient groups about the potential impact of the medicine on patients and carers.

After careful consideration, SMC decided the evidence from the company was not strong enough to be certain that darvadstrocel offers value for money to NHSScotland, this was despite applying extra flexibly as darvadstrocel is a medicine for a rare condition.

What does SMC's decision mean for me?

Darvadstrocel should not normally be prescribed on the NHS in Scotland for use as described above. Your doctor should talk to you about other treatment options available to you. If your doctor believes that darvadstrocel would be of benefit, he or she can make a request to prescribe it for you. All health boards have procedures in place to consider these requests. For further information see: Medicines in Scotland: What's the right treatment for me?

www.healthcareimprovementscotland.org/medicinesbooklet.aspx



More information

The organisations below can provide more information and support for people with Crohn's disease. SMC is not responsible for the content of any information provided by external organisations.

Crohn's and Colitis UK



<https://www.crohnsandcolitis.org.uk>



0300 222 5700

You can find out more about darvadstrocel in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.



<http://www.ema.europa.eu>

Date advice published: 8 July 2019

SMC No: (SMC2115)