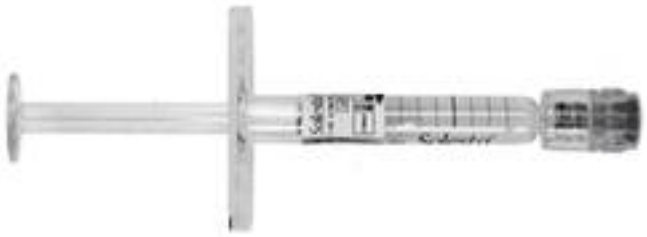
Consumer Information on: Solesta & #xae; - P100014

U.S. Food & Drug Administration

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.



Product Name: Solesta®
Manufacturer: Oceana Therapeutics, Inc.
Address: 2035 Lincoln Highway, Suite 2150, Edison, NJ 08817
Approval Date: May 27, 2011
Approval Letter: http://www.accessdata.fda.gov/ cdrh_docs/pdf10/p100014a.pdf [1]

What is it? Solesta is a sterile gel that is injected into the anus to treat the symptoms of fecal incontinence [2] (FI). It is composed of naturally-made materials called dextranomer (dex-stran-OH-mer) and sodium hyaluronate [3] (SO-dee-um hi•uhl-YOU•ro-nate).

How does it work? The Solesta gel is injected into a layer of tissue beneath the lining of the anus. Typically, there are 4 injections of Solesta during each treatment. Solesta is believed to work by building or "bulking" up tissue in the anal area. By narrowing the opening of the anus, the muscles used to prevent waste from escaping may be able to close better until the patient is ready to empty their bowels.

When is it used? Solesta is used for the treatment of FI in adult patients who have first tried and failed other "conservative" therapies, such as change in diet, fiber therapy or anti-diarrhea medicines.

What will it accomplish? Solesta does not work for everyone. In a clinical study of Solesta, more than half of the patients in the study who were treated with Solesta (72 out of 136) had the number of FI episodes cut in half as measured in a two-week period 6 months after treatment. However, about one-third (21 out of 70) of the patients who received a "sham" treatment (no Solesta injected) saw the same decrease in the number of FI episodes over the same period. At this time, it is not known for sure who will benefit from Solesta and who will not.

The most common risks of treatment with Solesta are mild to moderate pain or discomfort in the rectum or anus [4], (experienced by about 54 out of 197 patients) and minor to moderate bleeding or spotting from the rectum following treatment (experienced by about 39 out of 197 patients). Some experienced a fever (14 out of 197 patients), abdominal pain (6 out of 197 patients), or diarrhea or constipation (12 out of 197 patients) after treatment.

More serious risks include infection and inflammation of the anal tissues, but these are not common. In clinical studies, about 22 of 197 patients experienced infection or symptoms of infection and 14 of 197 patients experienced inflammation.

When should it not be used? Solesta is not to be used in patients aged 17 years and under.

Solesta is not for people who have:

- an infection or who are currently experiencing bleeding in the rectum or anus.
- previously received radiation treatment in the pelvic area.
- problems in the rectum or anus, such as tumors, abnormal anatomy, large dilated blood vessels (hemorrhoids) or cracks in the tissue (anal fissures).
- an active inflammation of the bowels (Crohn's disease or ulcerative colitis).
- trouble fighting off infection (immunodeficiency disorder such as HIV/AIDS) or who take medicine to suppress the immune system, such as those used in cancer treatments or organ transplants.
- a device or a material already placed in their rectum or anus.
- an allergy to any of the materials in the gel.

Additional Information: Summary of Safety and Effectiveness and labeling [5]are available online.

Other Resources:

- FDA News Release [6]

SOURCE [7]

Source URL (retrieved on *09/23/2014 - 9:13pm*):
http://www.mdtmag.com/news/2011/06/consumer-information-solesta-xae-p100014?qt-video_of_the_day=0

Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100014a.pdf
[2] http://digestive.niddk.nih.gov/ddiseases/pubs/fecalincontinence/index.htm
[3] http://www.merriam-webster.com/medlineplus/hyaluronate

[4] http://www.merriam-webster.com/art/med/digestio.htm
[5] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p100014
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