Poly- L- lactic acid

Brand Name: Sculptra
Drug Class: Opportunistic Infection and Other Drugs

Poly-L-lactic acid, also known as PLLA, is the main ingredient of Sculptra, also known as New-Fill. Sculptra is a powder that is mixed with water and then injected into the skin. Sculptra belongs to the class of medicines called dermal fillers. Injecting Sculptra into facial skin may give it a firmer, fuller appearance.

PLLA is used in many medical products such as stitches and screws used to repair broken bones. In Europe, Sculptra is called New-Fill and has been used by more than 100,000 people to treat wrinkles and scars.

HIV/AIDS-Related Uses

PLLA was approved by the FDA on August 3, 2004, for the treatment of facial fat loss (also called facial lipoatrophy). It continues to be studied for this use. Facial lipoatrophy is a condition in which people lose fat in their faces, especially in their cheeks and around their eyes and temples. People with HIV who take anti-HIV drugs may develop lipoatrophy.

PLLA is injected into the skin in areas where fat has been lost. It causes the skin to thicken, improves appearance of folds and sunken areas, and hides the fat loss. For most people who participated in PLLA clinical studies, the effects of treatment lasted for up to 2 years after the first treatment session.

This medicine does not cure or prevent HIV infection or AIDS and does not reduce the risk of passing the virus to other people.

Dosage Form/Administration

PLLA comes as a powder that is mixed with sterile water and then injected into the skin. Only a health care provider with special training should inject PLLA. Patients often need three to five injections of PLLA over the course of several weeks to achieve a visible effect.

Contraindications

Individuals should tell a doctor about any medical problems before using this medicine.

Possible Side Effects

Along with its desired effects, PLLA can cause some unwanted effects; not all of these effects are known at this time. Serious side effects have been rare and include lightheadedness and faintness, swelling of nodules developed under the skin, temporary numbing of the face, and severe allergic reaction. Individuals should tell a doctor if they have any of these side effects.

Less serious side effects include redness, swelling, and bruising in the area of the injection. Many patients have developed small nodules in the skin where PLLA was injected. The nodules are not visible and do not hurt. Individuals should tell a doctor if these side effects continue or are bothersome.

Drug and Food Interactions

A doctor should be notified of any other medications being taken, including prescription, nonprescription (over-the-counter), or herbal medications.

Clinical Trials

For information on clinical trials that involve Poly-L-lactic acid, visit the ClinicalTrials.gov web site at http://www.clinicaltrials.gov. In the Search box, enter: Poly-L-lactic acid AND HIV Infections.

Manufacturer Information

Poly-L-lactic acid
Dermik Laboratories, Inc.
1050 Westlakes Dr.
Berwyn, PA 19312
(484) 595-2700

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Manufacturer Information (cont.)

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For More Information

Contact your doctor or an AIDSinfo Health Information Specialist:

• Via Phone: 1-800-448-0440 Monday - Friday, 12:00 p.m. (Noon) - 5:00 p.m. ET

• Via Live Help: http://aidsinfo.nih.gov/live_help Monday - Friday, 12:00 p.m. (Noon) - 4:00 p.m. ET