

COSMODERM® and COSMOPLAST® dermal fillers

Important Treatment Considerations for Patients

COSMODERM® and COSMOPLAST® dermal fillers are approved for the correction of facial wrinkles, acne scars and other soft tissue contour deficiencies, as well as for the restoration of the lip border. The collagen in COSMODERM® and COSMOPLAST® dermal fillers is made of highly purified human-based collagen. Based on a clinical study conducted, no pre-treatment skin test is required. Temporary puffiness around the treatment site should be expected, especially with COSMODERM® dermal filler implant. You may also notice temporary blushing, slight bruising, and tenderness around the site with the use of either COSMODERM® or COSMOPLAST® dermal filler. This should resolve in a few days. Any redness and/or visible swelling that persists for more than a few days should be brought to the attention of your physician.

Strenuous exercise, excessive sun or heat exposure, and alcoholic beverages should be minimized until any initial swelling and redness has resolved. Exposure to any of these elements may cause temporary redness, swelling and/or itching at injections sites. COSMODERM® and COSMOPLAST® dermal fillers must not be used in people with a history of serious allergic (anaphylactic) reactions or a known allergy to lidocaine (a local anesthetic). An increased frequency of the potential to develop an allergic response to various collagens has been found in people with systemic connective tissue diseases, such as rheumatoid arthritis, juvenile rheumatoid arthritis, and progressive systemic sclerosis (scleroderma). The frequency and severity of such reactions with human collagen injections has not been determined. Local necrosis (tissue damage) is a rare event, which has been observed following bovine collagen implantation. Most necrosis reported through post-marketing surveillance of bovine dermal collagen have occurred after injection into the glabellar region of the face (between the eyebrows). COSMODERM® and COSMOPLAST® dermal fillers must not be injected into blood vessels; doing so may result in blockage of blood flow and loss of circulation in nearby areas.

Some physicians have reported the occurrence of connective tissue diseases such as rheumatoid arthritis, systemic lupus erythematosus, polymyositis (PM) and dermatomyositis (DM) after bovine collagen injections in people with no previous history of these disorders. A connection between bovine collagen and the onset of PM/DM, or the other connective tissue diseases listed, has not been established. The frequency and degree of such reactions after human collagen injections have not been determined.

Based on experience with bovine collagen implants, use of COSMODERM® 1 dermal filler should be limited to 30 mL over a 1-year period. Use of COSMODERM® 2 dermal filler should be limited to 15 mL over a 1-year period. Likewise, the use of COSMOPLAST® dermal filler should also be limited to 30 mL over a 1-year period. The combination of COSMODERM® 1 dermal filler and COSMODERM® 2 dermal filler, or of COSMODERM® dermal filler in conjunction with COSMOPLAST® dermal filler should be limited to 30 mL over a 1-year period. Safety of injecting greater amounts on an annual basis has not been established.

The safety of COSMODERM® and COSMOPLAST® dermal fillers use in people with a known allergy to bovine collagen has not been studied. Injectable collagen should be used with caution in people who have asthma, hay fever, eczema, or have a history of multiple allergies. As with all procedures involving an injection, COSMODERM® and COSMOPLAST® dermal fillers implantation carries a risk of infection. Active inflammatory skin conditions (e.g., cysts, pimples, rashes, or hives), or in areas where infection is present, require that treatment is postponed until the skin condition is under control. The safety of treatment during pregnancy or in infants and children has not been studied. COSMODERM® and COSMOPLAST® dermal fillers should be used with caution if you are taking medication that affects your immune system. If you are using substances that reduce blood clotting, such as aspirin or ibuprofen, you may, as with any injection, experience increased bruising or bleeding at injection sites. The safety and effectiveness of COSMODERM® and COSMOPLAST® dermal fillers implantation for use in lip augmentation has not been established. M913-02 07/06