

Hylaform®--Important Treatment Considerations for Consumers

In the U.S., Hylaform gel is indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds), and is generally well tolerated. The most commonly reported side effects are temporary injection site redness, bruising, swelling, pain and itching. Other side effects, such as lumps/bumps and tissue hardening have been reported rarely. Exposure of the treated area to excessive sun, UV lamp, and extreme cold weather should be minimized until any initial swelling and redness has resolved. If procedures such as laser treatment or a chemical peel are used before or after Hylaform gel treatment there is a possible risk of an inflammatory reaction at the implant site. This also applies if Hylaform gel is administered before the skin has healed completely after such a procedure. Hylaform gel should not be used in patients with known susceptibility to keloid formation, hypertrophic scarring or pigmentation disorders.

Patients using substances that can prolong bleeding may experience increased bruising or bleeding at injection sites. As with all transcutaneous procedures, Hylaform gel use carries a risk of infection and standard precautions used for injectable materials should be followed. Hylaform gel must not be injected into blood vessels; doing so may cause occlusion of the vessels and could cause infarction or embolization. Hylaform gel should be used with caution in patients on immunosuppressive therapy.

Hylaform gel is not intended for use in patients with a history of known allergy to avian (bird) proteins. The use of Hylaform gel in areas of the skin with any infection or inflammatory process (e.g., cysts, pimples rashes or hives), should be postponed until the conditions have been resolved. The safety of Hylaform gel in persons younger than 18 years of age, or in pregnant or breastfeeding women has not been tested. The safety and efficacy of Hylaform gel for use in lip augmentation and regions other than nasolabial folds has not been established. The safety of injecting greater than 20 mL of Hylaform gel per 130 lbs body mass per year has not been established. Long-term safety and effectiveness of Hylaform gel beyond one year has not been investigated in clinical trials.