INDICATIONS
SKINVIVE™ by JUVÉDERM® injectable gel is indicated for intradermal injection to improve skin smoothness of the cheeks in adults over the age of 21.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
This product should not be used in patients who have severe allergies, marked by a history of anaphylaxis or history or presence of multiple severe allergies, and should not be used in patients with a history of allergies to Gram-positive bacterial proteins or lidocaine contained in this product.

WARNINGS
- Do not inject into blood vessels. Introduction of this product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft-tissue fillers; for example, after insertion of the needle and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly, and apply the least amount of pressure necessary. Rare, but serious, adverse events associated with the intravascular injection of soft-tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms: changes in vision, signs of a stroke, blanching of the skin, unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and, possibly, evaluation by an appropriate healthcare professional specialist should an intravascular injection occur
- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled
- Injection site responses consist mainly of short-term inflammatory symptoms and generally resolve within 1 week. Refer to the ADVERSE EVENTS

PRECAUTIONS
- To minimize the risk of potential complications, this product should only be used by healthcare professionals who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection
- Discuss all potential risks of soft tissue injections with patients prior to treatment and ensure patients are aware of signs and symptoms of potential complications
- Limit patients to 20 mL of any JUVÉDERM® injectable gel per 60 kg (130 lbs.) body mass per year. The safety of injecting greater amounts has not been established
- This product is intended for improving skin smoothness and fine lines of the cheeks. The safety and effectiveness of use in other areas of the body have not been established
- Injection of more than 6.0 mL of this product (initial and touch-up treatment combined) for improvement of skin smoothness and fine lines of the cheeks has not been studied
- As with all transcutaneous procedures, injections of the product carry a risk of infection
- The safety for use during pregnancy, in breastfeeding females, and in patients under 22 years has not been established
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, or pigmentation disorders has not been studied
- This product should be used with caution in patients on immunosuppressive therapy

- Patients taking medications that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- Patients may experience late onset AEs with use of injectable gel implants, including this product
- This product should only be used by healthcare professionals who have appropriate experience and who are knowledgeable about the anatomy and the product for use in the face
- If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment, or before skin has healed from a procedure prior to treatment, there is a possible risk of eliciting an inflammatory reaction at the injection site

ADVERSE EVENTS

In clinical studies, injection site responses (ISRs) observed in >5% of treated subjects included redness, lumps/bumps, swelling, bruising, pain, tenderness, firmness, discoloration, and itching. Most ISRs were mild. Adverse events reported through postmarketing surveillance outside of the United States included inflammatory reaction, inflammatory nodule, unsatisfactory result, loss/lack of correction, allergic reaction, anxiety, vascular occlusion, infection, dry skin, increase/decrease in sensation, and abscess.

To report an adverse reaction with SKINVIVE™ by JUVÉDERM®, please call the Allergan® Product Support Department at 1-877-345-5372. Please see Directions for Use or visit SKINVIVEDFU.com for more information.

SKINVIVE™ by JUVÉDERM® is available only by a licensed physician or properly licensed practitioner.