

## **SKINVIVE™ by JUVÉDERM® Injectable Gel Important Information**

### **APPROVED USES**

SKINVIVE™ by JUVÉDERM® Injectable Gel is an intradermal injection to improve facial skin smoothness of the cheeks in adults over the age of 21.

### **IMPORTANT SAFETY INFORMATION**

#### **Are there any reasons why I should not receive SKINVIVE™ by JUVÉDERM® injectable gel treatment?**

Do not use this product if you have a history of severe reactions (anaphylaxis) or history or presence of multiple severe allergies or if you are allergic to lidocaine or the Gram-positive bacterial proteins used in this product, or if you have had previous allergic reactions to hyaluronic acid fillers.

#### **What warnings should my doctor advise me about?**

- One of the risks with dermal filler injection is the unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. Most of these events are irreversible. Tell your specialist immediately if you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, or unusual pain during or shortly after treatment
- The use of this product where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed, as this may delay healing or make skin problems worse
- The effectiveness of removal of any dermal filler has not been studied

#### **What precautions should my doctor advise me about?**

- Minimize strenuous exercise, exposure to extensive sun or heat, and alcoholic beverages within the first 24 hours following treatment. Exposure to any of these may cause temporary redness, swelling, and/or itching at the injection site
- Tell your doctor if you are using any medication that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners. As with any injection, this may increase bruising or bleeding at the injection site
- Tell your doctor if you are planning laser treatment, chemical peeling, or any other procedure after SKINVIVE™ by JUVÉDERM®. There is a possible risk of an inflammatory reaction at the treatment site
- This product is intended for improving skin smoothness of the cheeks. The safety and effectiveness for treatment in other areas of the body have not been established
- Tell your doctor if you are on therapy used to decrease the body's immune response. Use may result in an increased risk of infection

- Tell your doctor if you are pregnant or breastfeeding. The safety for use during pregnancy, or in women who are breastfeeding, has not been studied
- Tell your doctor if you have a history of excessive scarring (thick, hard scars). The safety of this product in patients with a history of excessive scarring has not been studied and may result in additional scars
- Tell your specialist if you have a history of pigmentation disorders, as use of this product in patients with a history of pigmentation disorders has not been studied and may result in changes in pigmentation

**What are the possible side effects of treatment?**

The most commonly reported side effects were redness, lumps/bumps, swelling, bruising, pain, tenderness, firmness, discoloration and itching. Most side effects will resolve within 7 days. If they persist longer, your physician may choose to treat them with medications, such as antibiotics, steroids, or hyaluronidase. Additionally, there have been reports of inflammation, nodules, unsatisfactory result, loss or lack of improvement, allergic reaction, anxiety, blood vessel blockage, infection, dry skin, increase or decrease in sensation, and abscess.