SKINVIVE™ by JUVÉDERM®
Patient Information Labeling

About SKINVIVE™ by JUVÉDERM®

Before beginning your treatments, please review this important information.

1. GLOSSARY

(Note that terms in the glossary are bold throughout this document)

Abscess—a swollen lump filled with pus

Anesthetic—a substance that reduces sensitivity to pain

Arnica—herbal ointment that is commonly used to treat pain, bruising, and swelling

BDDE—a small biodegradable compound added to crosslink the gel

Hyaluronic acid (HA)—a polysaccharide (sugar) that is naturally found in the body. HA hydrates the skin improving skin smoothness so the skin glows. SKINVIVE™ by JUVÉDERM® injectable gel is a modified form of the HA that is naturally in your body.

Hyaluronidase—an enzyme that breaks down hyaluronic acid

Lidocaine—a synthetic compound used as a local anesthetic to decrease pain

NSAIDs—nonsteroidal anti-inflammatory drugs, such as aspirin and ibuprofen

Pigmentation disorder—a medical condition that results in a change in skin color

Repeat injection—an additional treatment with SKINVIVE™ by JUVÉDERM® that is given after the effects of the initial treatment start to wear off in order to maintain the desired aesthetic outcome

Topical—cream or ointment applied to a certain area of the skin and affecting only the area to which it is applied

Touch-up—an additional injection of a small amount of SKINVIVE™ by JUVÉDERM® usually given about 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired aesthetic outcome

Vasodilators—drug that opens blood vessels

2. PRODUCT DESCRIPTION

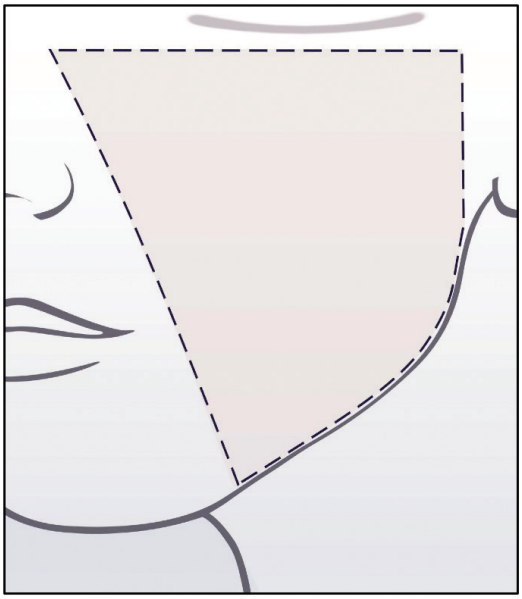
What is it?

SKINVIVE™ by JUVÉDERM® injectable gel is a smooth, clear, colorless **hyaluronic acid (HA)** gel that contains a small quantity of local **anesthetic (lidocaine)**. **HA** is a naturally occurring sugar found in the human body that retains moisture in the skin. BDDE (1,4-butanediol diglycidyl ether) is used as a crosslinking agent. SKINVIVE™ by JUVÉDERM® injectable gel is manufactured by crosslinking the HA gel using a small amount of BDDE, an organic substance the body will naturally break down.

How does it work?

SKINVIVE™ by JUVÉDERM® is injected into the cheeks using an ultrafine needle to restore skin smoothness (see Figure 1) for adults over the age of 21. The product injects HA to the cheeks which helps the skin retain its natural moisture and softness leading to an improvement in the skin smoothness of the cheeks. The **lidocaine** in the gel improves the comfort of the injection by reducing sensitivity to pain.

Figure 1: Treatment Area for SKINVIVE™ by JUVÉDERM®



3. CONTRAINDICATIONS

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

Your doctor will ask about your medical history to determine if a treatment regimen with SKINVIVE™ by JUVÉDERM® gel is right for you. You should not use SKINVIVE™ by JUVÉDERM® if:

- You have severe allergies, marked by a history of severe reactions (anaphylaxis) or history or presence of multiple severe allergies. Use may result in an allergic reaction.
- You are allergic to **lidocaine** or to the proteins used to make the **HA** in SKINVIVE™ by JUVÉDERM® (Gram-positive bacterial proteins). Use may result in an allergic reaction.
- If you have previous experience with allergic reactions to HA fillers. Use may result in an allergic reaction.

4. WARNINGS

What warnings should my doctor advise me about?

To help you understand the treatment risks, your doctor should discuss the following:

- One of the risks of using this product 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.
- 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, you should notify your health care practitioner immediately.
- The use of SKINVIVE™ by JUVÉDERM® where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of SKINVIVE™ by JUVÉDERM® where these are present could delay healing or make your skin problems worse.
- The effectiveness of removal of any dermal filler has not been studied.

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5. PRECAUTIONS

What precautions should my doctor advise me about?

The following are important treatment considerations for you to discuss with your doctor and understand to help avoid unsatisfactory results and complications:

- SKINVIVE™ by JUVÉDERM® should only be injected by doctors who have completed the necessary training for this treatment
- 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® injectable gel treatment. There is a possible risk of an inflammatory reaction at the treatment site.
- Tell your doctor which areas of your face you would like to have treated. 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 in controlled, clinical studies.
- 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 SKINVIVE™ by JUVÉDERM® injectable gel in patients with a history of excessive scarring has not been studied and may result in additional scars.
- Tell your doctor if you have a history of **pigmentation disorders**. The safety of SKINVIVE™ by JUVÉDERM® in patients with a history of **pigmentation disorders** has not been studied. Use in these patients may result in changes in pigmentation.

6. CLINICAL STUDY

How was the product studied?

To establish the safety and effectiveness of SKINVIVE™ by JUVÉDERM® injectable gel treatment for improving skin smoothness, 135 participants from the treatment group received injections of the product in the cheeks at the beginning of the study and 64 participants from the control group received injections 1 month later. To achieve the desired aesthetic outcome, a **touch-up** treatment was allowed 1 month after initial treatment. After 6 months, participants were offered a **repeat injection**.

To evaluate the safety of SKINVIVE™ by JUVÉDERM® injectable gel treatment, participants noted common side effects in daily diaries. Side effects were also reported by doctors based on office visits with each participant. These office visits included discussing any symptoms or complaints with the participants and assessing the smoothness of their skin on the cheeks. To evaluate the effectiveness of the product for improving skin smoothness and overall aesthetic appearance, 5-point scales were used. Participants used questionnaires to rate satisfaction with their skin after treatment.

7. BENEFITS

What will it accomplish?

The results of the SKINVIVE™ by JUVÉDERM® clinical study showed that the product improves skin smoothness of the cheeks.

What did the clinical study show?

SKINVIVE™ by JUVÉDERM® injectable gel treatment was found to effectively improve skin smoothness. The clinical study showed that the improvement lasts for 6 months in the majority of participants.

The study doctors reported the following:

- 58% of participants in the treatment group achieved a statistically superior improvement in skin smoothness on both cheeks at 1 month after treatment/touch-up compared to participants who did not receive treatment
- 56% of participants in the treatment group showed long-lasting, enduring improvement in skin smoothness on their cheeks at 6 months after treatment/touch-up
- 63% of treatment group participants showed improvement in the appearance of fine lines on their cheeks at 6 months after treatment/touch-up

Treatment group participants reported the following:

- Higher satisfaction with their skin through 6 months based on questionnaires
  - 74% of participants were satisfied with how radiant their facial skin looked at 1 month (after initial treatment or optional touch-up) and 63% at 6 months compared to 11% before treatment
  - 78% of participants were satisfied with how hydrated their facial skin looked at 1 month (after initial treatment or optional touch-up) and 72% at 6 months compared to 24% before treatment
  - 79% of participants were satisfied with how refreshed their facial skin made them look at 1 month (after initial treatment or optional touch-up) and 69% at 6 months when compared to 16% before treatment
  - 84% of participants were satisfied with how healthy their facial skin looked at 1 month (after initial treatment or optional touch-up) and 83% at 6 months when compared to 38% before treatment
  - 81% of participants were satisfied with how their pores looked at 1 month (after initial treatment or optional touch-up) and 69% at 6 months when compared to 30% before treatment

8. RISKS

What side effects were seen in the clinical study?

Participants reported side effects in 30-day daily diaries. Adverse events (AE) could also be reported by doctors at any time throughout the study.

Based on the clinical study, the likelihood of experiencing side effects after SKINVIVE™ by JUVÉDERM® injectable gel treatment is shown below in Table 1. Participants in the clinical study experienced side effects such as redness, lumps/bumps, swelling, bruising, tenderness, pain, firmness, discoloration, and itching at the injection sites, as reported in their 30-day daily diaries. These side effects were usually mild (causing little discomfort and no effect on daily activities) or moderate (causing some discomfort and effect on daily activities) in severity, although a few participants experienced severe side effects (causing great discomfort and effect on daily activities). Most of these side effects went away on their own within 30 days. Occasionally, some participants experienced side effects that lasted longer than 30 days. Three participants experienced lumps/bumps that went away on its own 12 to 15 months after treatment.

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Table 1: Injection Site Responses by Severity and Duration After Initial Treatment With SKINVIVE™ by JUVÉDERM® Occurring in > 5% of Treated Participants

Injection Site Response	Total % (n/N[a])	Severity[b]			Duration[c]				
		Mild % (n/N[a])	Moderate % (n/N[a])	Severe % (n/N[a])	1-3 Days % (n/N[a])	4-7 Days % (n/N[a])	8-14 Days % (n/N[a])	15-30 Days % (n/N[a])	> 30 Days % (n/N[a])
Any ISR	79.4% (158/199)	54.3% (108/199)	18.6% (37/199)	6.5% (13/199)	34.2% (68/199)	10.6% (21/199)	12.6% (25/199)	22.1% (44/199)	9.5% (19/199)
Redness	68.8% (137/199)	57.3% (114/199)	9.5% (19/199)	2.0% (4/199)	47.2% (94/199)	9.0% (18/199)	6.5% (13/199)	6.0% (12/199)	2.0% (4/199)
Lumps/Bumps	63.3% (126/199)	47.2% (94/199)	12.1% (24/199)	4.0% (8/199)	32.2% (64/199)	10.6% (21/199)	6.5% (13/199)	14.1% (28/199)	8.0% (16/199)
Swelling	61.3% (122/199)	49.7% (99/199)	9.5% (19/199)	2.0% (4/199)	40.7% (81/199)	7.5% (15/199)	9.0% (18/199)	4.0% (8/199)	1.5% (3/199)
Bruising	57.8% (115/199)	44.7% (89/199)	10.6% (21/199)	2.5% (5/199)	24.1% (48/199)	14.1% (28/199)	11.1% (22/199)	8.5% (17/199)	1.0% (2/199)
Pain	52.8% (105/199)	47.2% (94/199)	5.0% (10/199)	0.5% (1/199)	41.2% (82/199)	7.0% (14/199)	2.0% (4/199)	2.5% (5/199)	1.0% (2/199)
Tenderness	52.8% (105/199)	46.7% (93/199)	5.5% (11/199)	0.5% (1/199)	33.7% (67/199)	10.6% (21/199)	5.0% (10/199)	3.5% (7/199)	1.0% (2/199)
Firmness	47.2% (94/199)	40.7% (81/199)	5.5% (11/199)	1.0% (2/199)	32.7% (65/199)	5.5% (11/199)	5.5% (11/199)	3.5% (7/199)	2.0% (4/199)
Discoloration	34.2% (68/199)	27.1% (54/199)	6.5% (13/199)	0.5% (1/199)	19.6% (39/199)	3.5% (7/199)	4.5% (9/199)	6.5% (13/199)	2.5% (5/199)
Itching	25.1% (50/199)	22.6% (45/199)	1.5% (3/199)	1.0% (2/199)	15.1% (30/199)	6.0% (12/199)	2.0% (4/199)	2.0% (4/199)	1.5% (3/199)

[a] N denotes the number of participants who recorded responses in the diaries after initial treatment

[b] Maximum severity reported in the diary

[c] Duration is calculated based on the difference between the first and last date of occurrence

What adverse events were seen in the clinical study?

Adverse Events (AEs) were defined as "any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in participants, users, or other persons, whether or not related to the investigational medical device." An AE will be considered a treatment emergent adverse event (TEAE) if the AE began or worsened (increased in severity or became serious) after first treatment of SKINVIVE™ by JUVÉDERM®. A TEAE is considered a treatment-related TEAE if the event is considered related to the procedure or the study device by the doctor.

After SKINVIVE™ by JUVÉDERM® injectable gel treatment, 6 participants experienced 21 adverse events. These events included a scrape in the treated area as well as events that were the same as those reported in the daily diary, such as itching, redness, bruising, discoloration, pain, and lumps/bumps. Most of these adverse events were mild or moderate and went away on their own within 30 days. One participant experienced severe bruising after treatment.

No participants experienced adverse events after **repeat injection**.

Table 2: Participant-Level Summary of Treatment-Related AEs With SKINVIVE™ by JUVÉDERM®

TEAE	Participants % (n/N[a])	Severity			Outcome
		Mild % (n/N[a])	Moderate % (n/N[a])	Severe % (n/N[a])	
Injection Site Pruritus	1.5% (3/199)	1.0% (2/199)	0.5% (1/199)	0.0%	Recovered
Injection Site Erythema	1.0% (2/199)	1.0% (2/199)	0.0%	0.0%	Recovered
Injection Site Bruising	1.0% (2/199)	0.5% (1/199)	0.0%	0.5% (1/199)	Recovered
Injection Site Discoloration	0.5% (1/199)	0.5% (1/199)	0.0%	0.0%	Recovered
Injection Site Injury (Needle Abrasion)	0.5% (1/199)	0.5% (1/199)	0.0%	0.0%	Recovered
Injection Site Pain	0.5% (1/199)	0.0%	0.5% (1/199)	0.0%	Recovered
Injection Site Papule	0.5% (1/199)	0.5% (1/199)	0.0%	0.0%	Recovered[b]

[a] N denotes the number of participants who received initial treatment with SKINVIVE™ by JUVÉDERM®

[b] Participant reported recovery from the AE after database lock

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Table 3: Event-Level Summary of Treatment-Related AEs With SKINVIVE™ by JUVÉDERM®

TEAEs	Events % (n/N)	Time to Onset (Days after last treatment)					Duration (Days)	
		1-3 Days % (n/N)	4-7 Days % (n/N)	8-14 Days % (n/N)	15-30 Days % (n/N)	> 30 Days % (n/N)	≤ 30 Days % (n/N)	> 30 Days % (n/N)
Overall	100.0% (21)	57.1% (12/21)	23.8% (5/21)	0.0%	9.5% (2/21)	9.5% (2/21)	76.2% (16/21)	23.4% (5/21)
Injection Site Bruising	23.8% (5/21)	19.0% (4/21)	4.8% (1/21)	0.0%	0.0%	0.0%	19.0% (4/21)	4.8% (1/21)
Injection Site Pruritus	23.8% (5/21)	14.3% (3/21)	9.5% (2/21)	0.0%	0.0%	0.0%	19.0% (4/21)	4.8% (1/21)
Injection Site Papule	19.0% (4/21)	9.5% (2/21)	0.0%	0.0%	0.0%	9.5% (2/21)	9.5% (2/21)	9.5% (2/21)
Injection Site Erythema	14.3% (3/21)	4.8% (1/21)	9.5% (2/21)	0.0%	0.0%	0.0%	9.5% (2/21)	4.8% (1/21)
Injection Site Discoloration	9.5% (2/21)	0.0%	0.0%	0.0%	9.5% (2/21)	0.0%	9.5% (2/21)	0.0%
Injection Site Injury (Needle Abrasion)	4.8% (1/21)	4.8% (1/21)	0.0%	0.0%	0.0%	0.0%	4.8% (1/21)	0.0%
Injection Site Pain	4.8% (1/21)	4.8% (1/21)	0.0%	0.0%	0.0%	0.0%	4.8% (1/21)	0.0%

What other safety assessments were performed in the study?

In the study participants' vision were assessed before and after SKINVIVE™ by JUVÉDERM® treatment. There were no changes in vision reported due to treatment. Most participants at day 3 reported no disruption in their normal daily activities after SKINVIVE™ by JUVÉDERM® treatment.

What are other possible adverse events?

As with all skin-injection procedures, there is a risk of infection.

One of the risks with using this product 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.

Although most side effects will resolve within 7 days some side effects may persist longer. Your physician may choose to treat them with medications, such as antibiotics, steroids, or **hyaluronidase**.

What side effects have been reported through voluntary postmarket surveillance of SKINVIVE™ by JUVÉDERM® use outside of the United States?

The most commonly reported adverse events were the same as those reported by participants in the clinical study, such as lumps/bumps, swelling, redness, pain, and bruising. Additionally, there have been reports of blood vessel blockage, local reaction, rash, unsatisfactory result, skin discoloration, inflammation, skin inflammation, allergic reaction, itching, anxiety, dry skin, loss or lack of improvement, **abscess**, blister, infection, device migration, collection of blood outside of a blood vessel, necrosis, scarring, increase or decrease in sensation, headache, vision changes, numbness, and swollen lymph nodes.

Treatments for adverse events included antibiotics, muscle relaxants, blood thinners, antihistamines, **NSAIDs**, antivirals, **arnica**, **hyaluronidase**, hyperbaric oxygen treatment, ice, laser therapy, massage, radiofrequency therapy, steroids, ultrasound therapy, and warm compress.

Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

9. BEFORE PROCEDURE INFORMATION

What happens in the office before the injection?

Note that each doctor may have a unique process for assessing and treating patients. The following is an example of what you would likely experience with a typical procedure. Before the injection procedure, your doctor will ask you questions about your medical history, as well as your treatment goals. Your doctor will discuss whether you are an appropriate candidate for SKINVIVE™ by JUVÉDERM® injectable gel and review what to expect during and after treatment, including possible side effects. Your doctor will also examine your facial skin and may take photos. Different options for pain management will be discussed, and if pretreatment numbing is desired, a **topical** such as **lidocaine** cream, or other **anesthetic** agent may be used. The treatment area will be cleaned and then prepared with alcohol or other antiseptic. Your doctor may use a pen to mark your face, identifying the planned areas of injection.

10. PROCEDURE DESCRIPTION

What happens during the procedure?

After the first injection, your doctor will wait a few seconds to allow the **lidocaine** to take effect before moving forward with the rest of the treatment. SKINVIVE™ by JUVÉDERM® injectable gel will be injected in small amounts into the treatment area until the desired aesthetic outcome is achieved. Your doctor may massage the treatment area gently to assure that the product integrates in the skin and is evenly distributed for a smooth appearance. Ice may be applied for a brief period following treatment to minimize swelling and reduce pain.

11. Do the injections hurt?

Injections may cause some discomfort during and after the procedure. In the SKINVIVE™ by JUVÉDERM® clinical study, immediately after the injection, treatment group participants reported a median pain score of 3 on an 11-point scale where

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0 is no pain and 10 is worst pain imaginable. SKINVIVE™ by JUVÉDERM® contains **lidocaine** to reduce injection site pain. Your doctor may also choose to numb (anesthetize) the treatment area with a **topical** or injected numbing agent to further minimize discomfort.

12. AFTER PROCEDURE INFORMATION

What should I expect following the procedure?

In the SKINVIVE™ by JUVÉDERM® clinical study, the most common side effects were temporary responses at the treatment site such as redness, lumps/bumps, swelling, bruising, tenderness, and pain. These side effects usually lasted 7 days or less, but 1.5% of the side effects lasted more than 30 days or longer. See Section 7 for additional information on side effects seen in the clinical study.

Your doctor will also tell you what to expect following SKINVIVE™ by JUVÉDERM® injectable gel treatment. Within the first 24 hours, you should minimize strenuous exercise, exposure to extensive sun or heat, and alcoholic beverages. Exposure to any of the above may increase temporary redness, swelling, and/or itching at the injection site. If there is swelling, you may need to place an ice pack over the swollen area. You should ask your doctor when makeup may be applied after your treatment.

13. Will I need more than one treatment to achieve my desired results?

You should discuss your treatment goals and plan with your doctor. The regimen with SKINVIVE™ by JUVÉDERM® may require multiple treatments to achieve the desired results. In the clinical study, 73% of participants treated with SKINVIVE™ by JUVÉDERM® received a **touch-up** treatment 1 month after initial treatment in order to achieve the desired aesthetic outcome.

14. Do the results last forever?

No. While individual results may vary, in the clinical study, the results lasted for 6 months in most participants. **Repeat injections** are usually needed to maintain your desired result.

15. WHEN TO CALL YOUR DOCTOR

When should I call my doctor?

Call your doctor immediately if you have:

1) Changes in your vision
2) 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)
3) White appearance of the skin
4) Unusual pain during or shortly after treatment

Be sure to call your doctor if you have:

1) Significant pain away from the injection site
2) Any redness and/or visible swelling that lasts for more than a few days
3) Any side effect that occurs weeks or months after treatment
4) Any other symptoms that cause you concern

16. ADDITIONAL INFORMATION

If you believe that you have experienced a serious problem related to SKINVIVE™ by JUVÉDERM® injectable gel, you should call your doctor. You may also contact the Allergan Product Surveillance line during normal business hours at 1-877-345-5372 to report any side effects.

What should I do if I have additional questions?

For further questions and information, please call Allergan at 1-800-766-0171

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