SKINVIVE by JUVÉDERM®
Patient Information Labeling

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed physician or properly licensed practitioner

About SKINVIVE by JUVÉDERM® to Improve Neck Appearance

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 human body that retains moisture to hydrate the skin, which improves skin smoothness. 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

Improvement in skin smoothness—a noticeable increase in the evenness or softness of the skin texture compared with before treatment

Improvement of neck appearance—a noticeable overall improvement in how the neck looks compared with before treatment, which may include smoother, healthier looking skin, fewer visible lines, increased hydration, and a more youthful or refreshed appearance

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

Reduction in neck lines—a decrease in the number, depth, length, or visibility of lines on the neck compared with before treatment

Repeat treatment—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

Skin smoothness—the evenness or texture of the skin surface, including how smooth, soft, and less rough or crepey the skin looks and feels

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

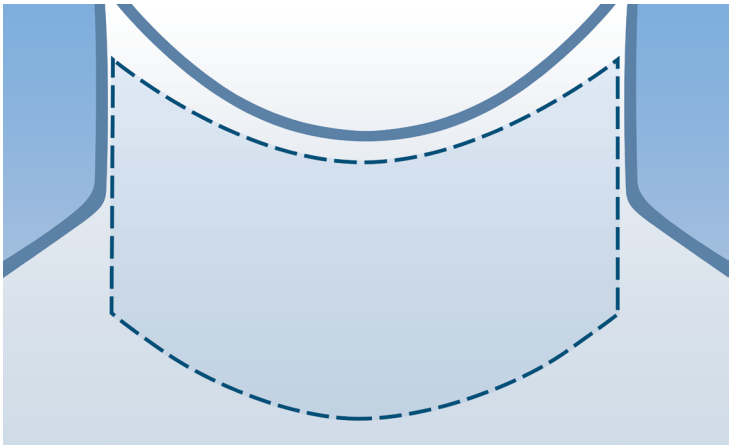
What is it?

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?

Neck wrinkles may develop due to natural aging, sun damage, weight loss, or the head-down position used for phones, tablets, and books commonly known as tech-neck. SKINVIVE by JUVÉDERM® is injected into the neck using an ultrafine needle or cannula and needle (see Figure 1) for adults over the age of 21. The product injected to the neck is **HA**, which reduces neck lines and helps the skin retain its natural moisture and softness leading to an improvement in neck appearance. The **lidocaine** in the gel improves the comfort of the injection by reducing sensitivity to pain.

Figure 1: Neck 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.

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- 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.

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:

- Avoid applying makeup for 12 hours after 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 before treatment 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 you would like to have treated. This product is intended for use in the cheek and neck areas (refer to the SKINVIVE by JUVÉDERM® Patient Label for Cheek Smoothness). 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 (immunosuppressive therapy). 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 neck appearance, 105 participants from the treatment group received injections of the product in the neck at the beginning of the study, and 43 of the 54 participants from the control group received injections 6 months later. To achieve the desired aesthetic outcome, a **touch-up** treatment was allowed 1 month after initial treatment. After 6 months, treatment group participants were offered a **repeat treatment**.

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 their neck appearance. To evaluate the effectiveness of the product for correcting neck lines and overall aesthetic appearance, 5-point scales were used. The main study assessment was evaluated by the study doctor. 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 reduces neck lines and improves neck appearance in 75%-80% of participants.

What did the clinical study show?

SKINVIVE by JUVÉDERM® injectable gel treatment was found to effectively reduce neck lines and improve neck appearance. The clinical study showed that the improvement lasts for 6 months in the majority of participants.

The study doctors reported the main study assessment:

- 75% of participants in the treatment group achieved improvement in neck lines at 1 month after treatment/ touch-up, which is statistically superior compared to participants who did not receive treatment

The study doctors also reported the following:

- 66% of participants in the treatment group showed long-lasting, enduring improvement in neck lines at 6 months after treatment/touch-up
- 80% of participants in the treatment group showed improvement in neck appearance at 6 months after treatment/ touch-up

Treatment group participants reported the following:

- Higher satisfaction with their skin through 6 months based on questionnaires
  - Compared to 34% before treatment, 81% of participants were not at all or a little bothered by how wrinkled their neck skin looks at 1 month after treatment and 63% at 6 months
  - Compared to 21% before treatment, 80% of participants were not at all or a little bothered by how deep their neck lines are at 1 month after treatment and 71% at 6 months
  - Compared to 21% before treatment, 71% of participants were not at all or a little bothered by how old their neck makes them look at 1 month after treatment and 61% at 6 months
  - Compared to 57% before treatment, 87% of participants were not at all or a little bothered by having to cover up their neck with clothing at 1 month after treatment and 77% at 6 months
  - Compared to 37% before treatment, 83% of participants were satisfied or very satisfied with the feel of their neck at 1 month after treatment
  - Compared to 30% before treatment, 74% of participants were satisfied or very satisfied with the smoothness (crepiness) of their neck skin at 1 month after treatment
  - 87% of participants would be willing to recommend the treatment at 1 month after treatment

8. ADVERSE EFFECTS

What side effects were seen in the clinical study?

Most participants in the clinical study experienced side effects such as redness, bruising, tenderness, lumps/bumps, swelling, firmness, pain, discoloration, and itching at the injection sites, as reported in their electronic diaries. These side effects were usually mild in severity, did not require treatment, and resolved within 2 weeks. Severe side effects were experienced by less than 5% of participants (7 of 147 reporting side effects). Based on the clinical study, the likelihood, severity, and duration of the side effects after initial treatment with SKINVIVE by JUVÉDERM® is shown below in Table 1 and Table 2. These events were reported less often after touch-up and repeat treatments.

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Table 1: Likelihood and Severity of Side Effects After Initial Treatment

Side Effect[a]	Likelihood of Experiencing Side Effect[b]	Maximum Severity of Side Effect		
		Mild %	Moderate %	Severe %
Any side effect	90 out of 100 people (90%)	42.9%	42.2%	4.8%
Redness	82 out of 100 people (82%)	63.9%	17.0%	0.7%
Bruising	78 out of 100 people (78%)	49.7%	25.2%	2.7%
Tenderness to Touch	78 out of 100 people (78%)	59.9%	17.0%	0.7%
Lumps/Bumps	76 out of 100 people (76%)	46.9%	27.2%	2.0%
Swelling	71 out of 100 people (71%)	56.5%	13.6%	0.7%
Firmness	65 out of 100 people (65%)	51.0%	12.9%	0.7%
Pain After Injection	63 out of 100 people (63%)	50.3%	12.2%	0.7%
Discoloration	50 out of 100 people (50%)	39.5%	8.8%	2.0%
Itching	35 out of 100 people (35%)	29.9%	3.4%	1.4%

[a]Occurring in >5% of participants

[b]Based on 147 participants who provided information about side effects after initial treatment

Table 2: Duration of Side Effects After Initial Treatment

Injection Site Response[a,b]	Duration[b]				
	1-3 Days %	4-7 Days %	8-14 Days %	15-30 Days %	> 30 Days %
Any side effect	6.1%	22.4%	24.5%	29.3%	7.5%
Redness	59.2%	15.6%	5.4%	1.4%	0%
Bruising	18.4%	25.9%	29.3%	3.4%	0.7%
Tenderness to Touch	46.3%	18.4%	8.2%	4.1%	0.7%
Lumps/Bumps	23.1%	13.6%	7.5%	25.2%	6.8%
Swelling	40.1%	18.4%	8.8%	2.7%	0.7%
Firmness	34.0%	14.3%	9.5%	5.4%	1.4%
Pain After Injection	44.9%	12.2%	4.1%	1.4%	0.7%
Discoloration	28.6%	12.9%	6.8%	2.0%	0%
Itching	21.8%	8.2%	4.1%	0%	0.7%

[a]Occurring in >5% of participants

[b]Based on 147 participants who provided information about side effects after initial treatment

What adverse events were seen in the clinical study?

Adverse events (any side effects to SKINVIVE by JUVÉDERM® reported by the doctors) were reported during the study. After SKINVIVE by JUVÉDERM® injectable gel treatment, 3% of participants (5 of 148 participants) experienced treatment-related adverse events. These events were all lumps/bumps such as those reported in the daily diary. All of these adverse events were mild in severity and went away on their own.

No participants experienced AEs after **repeat treatment.**

What other safety assessments were performed in the study?

Participants were assessed on visual acuity and functionality before and after completion of SKINVIVE by JUVÉDERM® initial, **touch-up**, and **repeat treatments**. Doctors did not find any significant changes in vision due to 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 low, 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 2 weeks, 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 AEs were the same as those reported by participants in the clinical study, such as lumps/bumps, swelling, firmness, 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.

In many cases, AEs resolved without any treatment. Treatments for AEs included antibiotics, muscle relaxants, blood thinners, **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 AEs 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.

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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 neck 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 another **anesthetic** agent may be used. The treatment area will be cleaned and then prepared with alcohol or another antiseptic. Your doctor may use a pen to mark your neck, 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.

Do the injections hurt?

Injections may cause some discomfort during and after the procedure. In the SKINVIVE by JUVÉDERM® clinical study to improve neck appearance, immediately after the injection, treatment group participants reported an average pain score of 1.9 on an 11-point scale where 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 ice or a **topical** or injected numbing agent to further minimize discomfort.

11. 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, bruising, tenderness to touch, lumps/bumps, swelling, firmness, and pain after injection. These side effects usually lasted 2 weeks or less. See Section 8 for additional information on side effects seen in the clinical study.

Your doctor will tell you what to expect following SKINVIVE by JUVÉDERM® injectable gel treatment. Avoid applying makeup for 12 hours after 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.

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, 69% 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.

Do the results last forever?

No. While individual results may vary, in the clinical study to improve neck appearance, the results lasted up to 6 months in a majority of participants (66%) treated with SKINVIVE by JUVÉDERM. **Repeat treatments** are usually needed to maintain your desired result.

12. 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, or
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, or
4) any other symptoms that cause you concern

You may also contact the Allergan Product Surveillance line at 1-877-345-5372 to report any side effects during the following business hours: 8 am to 5 pm CST Monday – Friday.

13. ADDITIONAL INFORMATION

What if I experience a problem?

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 Aesthetics at 1-800-766-0171.

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