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saypha® ChIQ™

Patient Information Guide

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About saypha ChIQ

This guide will help you decide whether treatment with saypha ChIQ is right for you. This information does not take the place of a discussion with your doctor. This guide will answer some questions you may have about saypha ChIQ treatment.

- Only you and your doctor can decide whether saypha ChIQ is right for you. Other treatments are available to you to correct lost facial volume and you may discuss these treatment options with your doctor.
- Please read all the information in this guide and discuss any questions with your doctor before you are treated with saypha ChIQ.

1 GLOSSARY

Adverse Event (AE) – harmful event, such as a bad reaction to a medication or treatment

Anaphylaxis – severe allergic reaction

Anesthetic – an ingredient that reduces sensitivity to pain

Angioedema – swelling under the skin

BDDE – substance used to cross-link the hyaluronic acid

Capsular contracture – scar tissue around an implant

Cross-linking – a process in which hyaluronic acid chains are connected to form a network

Dermal Filler – a substance that is injected in the skin to create a smoother and/or fuller appearance in the face.

Edema – swelling

Fibrosis – deposition of connective tissue during wound healing causing thickening of the skin

Gram-positive bacterial proteins – remnants of protein from the bacteria that produce the hyaluronic acid used in saypha ChIQ

Granuloma – small lump under the skin due to an immune response

Hyaluronic acid (HA) – a naturally occurring sugar found in the body that gives the skin moisture, volume, and elasticity

Hyaluronidase – an enzyme that breaks down hyaluronic acid

Inflammatory reaction – a localized response to injury, typically including pain, heat, redness and swelling

Lidocaine – a commonly used local anesthetic to numb the skin

Midface – region between the upper and lower third of the face

Necrosis – death of living tissue (skin)

Papule – a small lump under the skin

Paresthesia – feeling like pins and needles

Phlebitis – irritation or inflammation of the vein

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

Presyncope – a condition of feeling faint and almost passing out

Repeat treatment – an additional treatment with the product that is given after the effects of the initial treatment have worn off to maintain the desired result

Scleroderma – an autoimmune disease that causes inflammation and thickening in the skin

Sebaceous hyperplasia – benign enlargement of glands in the skin

Topical – cream or ointment applied to a certain area of the skin and affecting only the applied area

Touch-up treatment – an additional injection of a small amount of dermal filler usually given about 2 weeks to 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired result.

Vascular occlusion – blockage of a blood vessel

2 PRODUCT DESCRIPTION

What is saypha ChIQ?
saypha ChIQ is a 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 gives the skin moisture, volume, and elasticity. saypha ChIQ is **cross-linked** with **BDDE** to help form a network of **HA**. This results in a specialized smooth gel with long lasting results at the treatment site.

How does saypha ChIQ work?
saypha ChIQ is a colorless gel that is injected directly into skin using an ultrafine needle or cannula for cheek augmentation to correct volume deficit in the **midface**. The **lidocaine** in the gel reduces discomfort from the injection.

3 CONTRAINDICATIONS

Are there any reasons why I should not receive saypha ChIQ?
Your doctor will ask about your medical history to determine if saypha ChIQ is right for you. You should not receive saypha ChIQ if:

- You have severe allergies, marked by a history of **anaphylaxis** or history or presence of multiple severe allergies. Use may result in an allergic reaction.
- You are allergic to **lidocaine**. Use may result in an allergic reaction.
- You have a history of allergies against **gram-positive bacterial proteins**. Use may result in an allergic reaction.
- You have a bleeding disorder.

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 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, skin **necrosis**, temporary scabs, or permanent scarring of the skin.
- The use of saypha ChIQ where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of

saypha ChIQ where these are present could delay healing or make your skin problems worse.

- **Inflammatory reactions**, **anaphylaxis**, **edema**, implant migration, blisters, scarring, **papules,** and delayed onset of **granulomas** have been reported following the use of **dermal fillers**.

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:

- 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 treatment with saypha ChIQ. This may lead to an increased risk of **inflammatory reaction** at the injection site.
- Tell your doctor which areas of your face you would like to have treated. This product helps to treat the **midface**. The safety and effectiveness for other treatment areas have not been established in controlled clinical studies.
- Tell your doctor about any medicines you are taking. You may have a greater risk of developing an infection if you use saypha ChIQ while taking any medication that reduces your body's natural defense system. This includes medicines to treat HIV and AIDS, autoimmune diseases such as rheumatoid arthritis and Crohn's disease, chemotherapy for cancer, and steroids like prednisone. Use may result in an increased risk of infection.
- Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. The safety of saypha ChIQ has not been studied in women who are pregnant or breastfeeding.
- saypha ChIQ should only be used in adults over the age of 21.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars) or **pigmentation disorders**. The safety of saypha ChIQ in patients with a history of excessive scarring or **pigmentation disorders** has not been studied. Use in these patients may result in additional scars and skin color changes.

6 CLINICAL STUDY

How was saypha ChIQ studied?
To establish the safety and effectiveness of saypha ChIQ for cheek augmentation and to restore **midface** volume deficit, 322 subjects were treated with saypha ChIQ and 161 subjects with another **dermal filler** (control). To achieve subjects' desired results, an optional **touch-up treatment** was allowed 2 weeks after initial treatment. The follow-up period consisted of safety and effectiveness follow-up visits after treatment at 2, 4, 8, 16, 24, 36 and 48 weeks. Subjects were eligible for a **repeat treatment** with saypha ChIQ at 48 weeks or beyond, with follow-up for 6 months after treatment.

The median injection volume (both sides combined) of saypha ChIQ used in the clinical study to achieve optimal outcomes at initial treatment was 4.0 mL. At **touch-up treatment**, approximately 1.0 mL was used. For the **repeat treatment**, only about half of the median injection volume was required to achieve optimal outcome (2.0 mL). At **touch-up treatment** after **repeat treatment**, approximately 1.0 mL was used.

To evaluate the safety of saypha ChIQ, subjects noted common side effects in daily diaries. Side effects were also reported by doctors during office visits with each subject. These office visits included discussing any symptoms or complaints with the subjects and assessing the appearance of the subjects' **midface**. To evaluate the effectiveness of the product, a 5-point **Midface** Volume Deficit Severity Scale was used.

7 BENEFITS

What will saypha ChIQ do for me?
The results of the saypha ChIQ clinical study showed that the product will temporarily restore **midface** volume deficit.

What did the clinical study show?
The clinical study results of saypha ChIQ showed that the product helps to temporarily restore volume to the **midface** area, promoting a more youthful facial appearance. The clinical study showed that the effect of saypha ChIQ lasted up to 48 weeks in the majority of subjects. The study doctors assessed the improvement in **midface** volume for subjects treated with saypha ChIQ or the control **dermal filler** over the course of the study. The results are shown below.

The study doctors reported a 1-point or greater improvement on a 5-point **Midface** Volume Deficit Severity Scale in:

Study timepoint	Percentage of subjects with 1-point or greater improvement	
	saypha ChIQ	Control
4 weeks	97%	97%
8 weeks	98%	97%
16 weeks	97%	97%
24 weeks	97%	89%
36 weeks	90%	80%
48 weeks	72%	63%

For the treatment with saypha ChIQ, subjects reported:

- High satisfaction with the outcome with an average score of 64 out of 100 at 48 weeks after treatment
- Improvement in the appearance of their cheeks related to symmetry, smoothness, attractiveness, contour and youthful fullness compared prior to treatment
    - Average improvement from 34 to 75 points on a 100-point scale at 24 weeks
    - Average improvement from 34 to 70 points on a 100-point scale at 48 weeks
- 76% rated themselves as showing aesthetic improvement at 48 weeks after treatment

8 RISKS

What side effects were seen in the clinical study?
Subjects reported side effects in daily diaries over 28 days. **Adverse events** could also be reported by doctors at any time throughout the study.

Based on the clinical study, the likelihood of experiencing side effects after treatment with saypha ChIQ is shown below in Table 1. Less than 29% of subjects in the clinical study experienced a side effect such as tenderness to touch, firmness, lumps/bumps, swelling, pain after injection, bruising, redness, discoloration, and itching, as reported in their diaries. These side effects were usually mild (barely noticeable) or moderate (very noticeable) in severity, although some subjects experienced severe side effects (severe discomfort). Most of the side effects went away on their own within 2 weeks.

Table 1. Side Effects After Treatment[a]	
Side Effect	**Likelihood of Experiencing Side Effect**
Tenderness to touch	25 out of 100 people (25%)
Firmness	25 out of 100 people (25%)
Lumps/bumps	24 out of 100 people (24%)
Swelling	23 out of 100 people (23%)
Pain after injection	20 out of 100 people (20%)
Bruising	20 out of 100 people (20%)
Redness	18 out of 100 people (18%)
Discoloration	10 out of 100 people (10%)
Itching	5 out of 100 people (5%)

[a] Based on 312 subjects who provided information about side effects after their initial treatment

What adverse events (AEs) were seen in the clinical study?

Adverse events were reported over the course of the study. After treatment with saypha ChIQ, most of the **AEs** were rated as mild or moderate. Many **AEs** reported in more than one subject were the same as those reported as side effects in the diaries, such as headache, discomfort when touched, injection site bruising, injection site pain, changes in chewing and drinking, injection site mass, injection site swelling, jaw discomfort, dizziness, and lumps/bumps. One subject experienced a serious AE that was classified as possibly related to medical device and procedure: **vascular occlusion** in the skin. Following **AEs** were reported in only one subject each: difficulty speaking, injection site coldness, injection site discomfort, itching, muscle spasm, oral pain, sinus pressure, skin burning sensation and toothache.

What are other possible AEs?

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, skin **necrosis** or permanent scarring of the skin.

Although most side effects will go away with time, your doctor may choose to treat them with medications, such as antibiotics, steroids, or **hyaluronidase** (an enzyme that breaks down **HA**).

The following undesired side effects have been observed with similar viscoelastic implants and are considered as potential risks for this device: abscess, **angioedema**,

bacterial infection, bleeding, **capsular contracture**, dizziness, eye swelling, fever, **fibrosis**, hematoma, joint stiffness, malaise, muscle twitching, nausea, nerve damage, numbness, **paresthesia**, pain in jaw, peeling, **phlebitis**, physical asymmetry, **presyncope**, rash, **scleroderma**, **sebaceous hyperplasia**, sensory disturbance, skin disorders, syncope/fainting, tactile disorder, temperature intolerance.

9 BEFORE PROCEDURE INFORMATION

What happens in the doctor's office before the injection?

Note that each doctor may have a unique process for assessing and treating patients. The following is an example of a typical procedure. Before the injection, 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 saypha ChIQ and review expectations during and after treatment, including possible side effects. Your doctor will also examine your skin in and around the treatment area and may take photos. Your doctor may also test your vision and repeat this test after the treatment. Different options for additional pain management will be discussed and if pre-treatment numbing is desired, a **topical** such as **lidocaine** cream or other **anesthetic** 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 injection areas.

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. saypha ChIQ 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 ensure that the product integrates in the skin and is evenly distributed for a smooth, natural look. Ice may be applied for a brief period following treatment to minimize swelling and reduce pain.

Do the injections hurt?

The injections may cause some discomfort during and after the treatment. In the saypha ChIQ clinical study, subjects on average rated pain after injection at or below 1 on a scale from 0 to 10, where 0 is no pain and 10 is worst pain imaginable. In general, the pain went away within 15 minutes. saypha ChIQ 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.

11 AFTER PROCEDURE INFORMATION

What should I expect following the procedure?
In the saypha ChIQ clinical study, the most common side effects were tenderness to touch, firmness, lumps/bumps, swelling, pain after injection, bruising, redness, discoloration, and itching. These side effects usually lasted up to 14 days. See Section 8 for additional information on side effects seen in the clinical study.

Your doctor will give you specific after treatment care instructions. Within the first 24 hours, you should avoid or minimize hard (strenuous) exercise and exposure to extensive sun or heat. 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 ice over the swollen area. You should avoid massaging the treatment area for 2 days after the procedure. You should ask your doctor when cosmetics 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. In the clinical study, 67.7% of the subjects treated with saypha ChIQ received a **touch-up treatment** 2 weeks after initial treatment to achieve the desired results. The timepoint of this **touch-up treatment** may depend on your doctor's assessment.

How long do the results last?
While individual results may vary, in the clinical study, the results lasted up to 48 weeks in most subjects treated with saypha ChIQ. After this, **repeat treatment** is usually needed to re-gain your desired result. You should consider that the product may remain in the treated area for about two years after treatment.

12 WHEN TO CALL YOUR DOCTOR

When should I call my doctor?
Call your doctor 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
- Unusual pain during or shortly after treatment

Be sure to call your doctor if you have:

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

13 ADDITIONAL INFORMATION

If you believe that you have experienced a serious problem related to saypha ChIQ, you should call your doctor. You may also contact Product Support at [*placeholder for telephone number*] (USA Toll Free) or [*placeholder for telephone number*] (Local) to report any side effects. You may also report the occurrence of any **adverse events** to the Food and Drug Administration through the MedWatch Program: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.

What should I do if I have additional questions?

For further questions and information, please call [*placeholder for telephone number*]. [*placeholder for website*]

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