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**saypha® MagIQ™**

**Patient Information Guide**

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## **About saypha MagIQ**

This guide will help you decide whether treatment with saypha MagIQ 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 MagIQ treatment.

- Only you and your doctor can decide whether saypha MagIQ is right for you. Other treatments are available to correct wrinkles and folds 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 MagIQ.

## **1. GLOSSARY**

**Anaphylaxis** – severe allergic reaction

**Anesthetic** – an ingredient that reduces sensitivity to pain

**Angioedema** – swelling under the skin

**BDDE** – substance used to crosslink 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

**Erythema** – redness of the skin

**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 MagIQ

**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

**Nasolabial folds (NLFs)** – the lines or wrinkles that run from the corners of the nose downward toward the corners of the mouth

**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.

## 2. PRODUCT DESCRIPTION

### What is saypha MagIQ?

saypha MagIQ 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 MagIQ is **cross-linked** with **BDDE** to help form a network of **HA**.

### How does saypha MagIQ work?

saypha MagIQ is a colorless gel that is injected directly into skin using an ultrafine needle to help smooth away **nasolabial folds (NLF)**. The **lidocaine** in the gel reduces discomfort from the injection.

## 3. CONTRAINDICATIONS

### Are there any reasons why I should not receive saypha MagIQ?

Your doctor will ask about your medical history to determine if saypha MagIQ is right for you. You should not receive saypha MagIQ 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 to **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 MagIQ where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of saypha MagIQ 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 MagIQ. 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 treat **nasolabial folds**. 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 MagIQ 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 MagIQ has not been studied in women who are pregnant or breastfeeding.
- saypha MagIQ 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 MagIQ 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 MagIQ studied?

To establish the safety and effectiveness of saypha MagIQ for smoothing the appearance of facial wrinkles and folds, 270 subjects were treated with saypha MagIQ in one **nasolabial fold (NLF)** and another dermal filler (control) in the opposite **NLF**. To achieve the 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, 12, 24, 36, 48 weeks and beyond. Subjects were eligible for a repeat treatment with saypha MagIQ at 36 weeks or beyond, with follow-up for 3 months after treatment.

The average amount of saypha MagIQ used in the clinical study to achieve optimal outcomes at initial treatment was 1.2 mL for one NLF. At **touch-up treatment**, approximately 0.4 mL was used.

To evaluate the safety of saypha MagIQ, subjects noted common treatment related reactions in daily diaries. Treatment related reactions 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' **NLFs**. To evaluate the effectiveness of the product, a 5-point Wrinkle Assessment Scale was used.

Outside the US another study with saypha MagIQ for the correction of moderate to severe **NLFs** was conducted treating a total of 60 subjects.

## 7. BENEFITS

### What will saypha MagIQ do for me?

The results of the saypha MagIQ clinical study showed that the product will temporarily smooth and reduce the appearance of moderate to severe facial wrinkles and folds such as **NLFs**.

### What did the clinical study show?

saypha MagIQ was found to effectively smooth and reduce the appearance of moderate to severe facial wrinkles and folds.

At office visits after treatment, doctors examined and evaluated the changes in appearance of treated wrinkles and reported visible improvements in 93% of patients at 12 weeks, in 82% of patients at 24 weeks and 81% of patients at 36 weeks, respectively.

When asked to rate their satisfaction with the treatment outcome, patients on average reported high satisfaction with the improvement in the appearance of their **NLFs**. This assessment was based on how bothered they were with the depth of their **NLFs**, how the **NLFs** looked when relaxed and smiling, how old their **NLFs** make them look, and how their **NLFs** look compared with other people their age.

## 8. RISKS

### What common treatment related reactions were seen in the clinical study?

Based on the clinical study, the likelihood of experiencing reactions after treatment with saypha MagIQ is shown below in Table 1. The majority of subjects (95.3%<sup>1</sup>) in the clinical study experienced common reactions such as firmness, swelling, lumps/bumps, tenderness to touch, redness, bruising, pain after injection, itching, and discoloration. These reactions were usually mild (barely noticeable; 35.7%<sup>1</sup>) or moderate (very noticeable; 45.9%<sup>1</sup>). In some cases severe treatment reactions (causing severe discomfort; 13.7%<sup>1</sup>) were reported. Most reactions (72.2%<sup>1</sup>) went away on their own within 2 weeks. 23.1% of subjects reported reactions beyond 2 weeks after treatment.

<b>Type</b>	<b>Likelihood</b>
Firmness	80 out of 100 people (80%)
Swelling	76 out of 100 people (76%)
Lumps/bumps	71 out of 100 people (71%)
Tenderness to touch	70 out of 100 people (70%)
Redness	68 out of 100 people (68%)
Bruising	67 out of 100 people (67%)
Pain after injection	46 out of 100 people (46%)
Itching	29 out of 100 people (29%)
Discoloration	25 out of 100 people (25%)
Other	19 out of 100 people (19%)

<sup>a</sup> Based on 255 subjects who provided information about treatment reaction after their initial treatment

<sup>1</sup> Percentages calculated from 255 subjects who reported on treatment reactions after initial treatment

The following additional treatment related reactions were also reported during the study (maximum duration in parentheses): headache (2 days), contusion (14 days), swelling (14 days), eyelid margin crusting (10 days), discomfort (14 days), redness (5 days), feeding disorder (6 days) and itching (38 days). One case of mild **erythema** was reported starting 91 days after initial treatment and was ongoing at the end of the study without intervention taken. A mild **papule** was reported for a single patient 44 days after initial treatment and went away on its own after 211 days.

### **What are other possible Treatment related reactions?**

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 treatment related reactions 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**).

### **What additional treatment related reactions have been reported through voluntary post-market surveillance of saypha MagIQ use outside of the United States?**

saypha MagIQ has been sold outside the United States since 2016 under different brand names. All treatment related reactions obtained through reports by doctors are listed in descending order of frequency: device dislocation, skin inflammation/irritation, herpes simplex reactivation, hypersensitivity/allergic reaction, hemorrhage/bleeding, **phlebitis**, **granuloma**, **necrosis**.

The following undesired treatment related reactions have been observed with similar dermal fillers and are considered as potential risks for this device: abscess, **angioedema**, bacterial infection, **capsular contracture**, dizziness, fever, **fibrosis**, malaise, nausea, numbness, **paresthesia**, peeling, physical asymmetry, **presyncope**, rash, **scleroderma**, **sebaceous hyperplasia**, skin burning sensation, skin disorders, syncope/fainting, tactile disorder.

## 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 MagIQ and review expectations during and after treatment, including possible treatment related reactions. 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 pretreatment numbing is desired, a **topical** such as **lidocaine** cream or another **anesthetic** 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 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 MagIQ 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 MagIQ clinical study, subjects on average rated pain immediately after injection from 0.1 to 0.4 on an 11-point scale where 0 is no pain and 10 is worst pain imaginable. In general, the pain went away within 15 minutes. saypha MagIQ 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 MagIQ clinical study, the most common treatment related reactions were firmness, swelling, lumps/bumps, tenderness to touch, redness, and bruising. These reactions usually lasted up to 14 days. See Section 8 for additional information on treatment related reactions 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, approximately half of the subjects (54%) treated with saypha MagIQ 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 MagIQ. After this, **repeat treatment** is usually needed to re-gain your desired result.

## 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 reactions that occur 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 MagIQ, you should call your doctor. You may also contact Product Support at 1-800-636-7546 (USA Toll Free) to report any treatment related reactions. You may also report the occurrence of any treatment related reactions 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 1-800-636-7546.

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