Informed Consent

Kybella® – Deoxycholic Acid Injection

©2020 American Society of Plastic Surgeons®. Purchasers of the *Informed Consent Resource* are given a limited license to modify documents contained herein and reproduce the modified version for use in the Purchaser's own practice only. The American Society of Plastic Surgeons® does not authorize the use of these documents for purposes of any research or study. All other rights are reserved by the American Society of Plastic Surgeons®. Purchasers may not sell or allow any other party to use any version of the *Informed Consent Resource,* any of the documents contained herein or any modified version of such documents.

INSTRUCTIONS

This is an informed consent document to help you learn about deoxycholic acid injection therapy. It will outline the risks and other treatments.

This document covers injections using the following.

___**Kybella®** – Deoxycholic acid is a manmade substance that helps your body absorb fat. It kills fat cells when injected into the body.

It is important that you read the whole document carefully. Please initial each page. Doing so means you have read the page. Signing the consent agreement means that you agree to the surgery that you have talked about with your plastic surgeon.

GENERAL INFORMATION

In this procedure, a substance called deoxycholic acid is injected into your body. It can make you look better by removing fat in some areas. The US Food and Drug Administration (FDA) has approved deoxycholic acid to treat moderate to severe fat under the chin (double chin).

Injections are different for each patient. It can vary depending on your needs. They can't stop you from aging. They can only make the extra fat under the chin less obvious.

You may need multiple treatments to get the results you want.

OTHER TREATMENTS

There are other ways to treat a double chin. You can also choose not to treat it at all. Other options include liposuction. You can also go in for noninvasive or less invasive treatments that cool or heat the fat. Some surgeries can also remove extra fat under the chin. Every treatment has its own risks and problems.

RISKS OF DEOXYCHOLIC ACID INJECTIONS

Every procedure has risks. It is important that you understand the risks and the possible problems that can result from them. All procedures have limits. Choosing to have this procedure means comparing the risks and benefits. Most patients do not face the issues you'll learn about, but you must talk about them with your plastic surgeon. Make sure you understand the risks and possible outcomes of deoxycholic acid injections. You can also get more information from the package-insert sheets given by the product's manufacturers.

SPECIFIC RISKS OF DEOXYCHOLIC INJECTIONS

Bleeding and Bruising:

Although it is rare, you may have bleeding after a Kybella® injection or the local anesthesia used during your treatment. You might see bruising or your blood vessels may be injured. If you have bleeding, you might need emergency treatment or surgery. Taking certain medications and supplements may tend to cause bleeding. These include aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other herbs, supplements, and homeopathic remedies. Do not take any of these for seven days before or after your injections.

Swelling:

It's normal to have some swelling (edema) after your injections. This usually goes away after a few days. If the swelling doesn't go away, you may need medical treatment.

©2020 American Society of Plastic Surgeons®

This form is for reference purposes only. It is a general guideline and not a statement of standard of care. Rather, this form should be edited and amended to reflect policy requirements of your practice site(s), CMS and Joint Commission requirements, if applicable, and legal requirements of your individual states. The ASPS does not certify that this form, or any modified version of this form, meets the requirements to obtain informed consent for this procedure in the jurisdiction of your practice.

Pain:
You may have pain after injections. It doesn't last very long—usually no more than a week. Please talk to your doctor about pain management.

Numbness:
You may have numbness around the injection area. This should go away in a few days.

Difficulty Swallowing (Dysphagia):
In rare cases, you might have trouble swallowing after your treatment. This usually goes away as your swelling goes down.

Facial Nerve Damage:
In rare cases, the nerves around the treatment area may be injured by the injection. This can make the muscles there weak. Nerve problems should get better in a few days. It may also take up to a year to heal.

Skin Hardness:
You might notice your skin feeling hard around the treatment area. This is very rare. This usually goes away in a few days.

Needle Marks:
It's normal to see needle marks from the injections. These usually go away in a few days.

Hair Loss:
You might notice hair loss in the area that is treated with deoxycholic acid. The hair may grow back after a few months. It is also possible for the hair loss to be permanent.

Skin Sensitivity:
You might notice a skin rash, itchiness, tenderness, or swelling after your injections. After treatment, you should protect your skin from too much sun or UV lamp exposure and extreme cold until the swelling or redness has gone away.

Erythema (Skin Redness):
It's normal for your skin to be red after injections. This usually goes away after a few days.

Infection:
In rare cases, you may get a bacterial, fungal, or viral infection after having a Kybella® injection. If you get any type of skin infection, you might need more treatment including antibiotics.

Asymmetry:
Everyone's face is different on each side. This asymmetry is normal. It may not be possible to get or maintain perfect symmetry with Kybella® injections. Each side of your face might react differently to the treatment. You may need more injections to fix this.

Necrosis (Tissue Death):
It is very rare to see loss of skin or deeper soft tissues after Kybella® injections. Skin loss can result in scars that don't look very good. If you have scarring, you may need more treatment or surgery.

©2020 American Society of Plastic Surgeons®

This form is for reference purposes only. It is a general guideline and not a statement of standard of care. Rather, this form should be edited and amended to reflect policy requirements of your practice site(s), CMS and Joint Commission requirements, if applicable, and legal requirements of your individual states. The ASPS does not certify that this form, or any modified version of this form, meets the requirements to obtain informed consent for this procedure in the jurisdiction of your practice.

Allergic Reactions and Hypersensitivity:

You may have allergies and reactions of shock (anaphylaxis). These injections should not be used if you have a history of multiple severe allergies, a history of anaphylaxis, or allergies to gram-positive bacterial proteins. Severe allergies are rare but may occur. If this happens, you may need more treatment.

Poor Results:

Kybella® injections alone may not give you the results you want. Your double chin may not go away completely. You could respond badly to the injection. You may need more injections. Your doctor may also suggest other treatments, including surgery. Results you don't like may NOT improve with more treatment.

Unknown Risks:

We don't know the long-term effects of deoxycholic acid. We may find out about more risks or problems related to using Kybella® in the future.

Pregnancy and Nursing Mothers:

There are no animal studies that demonstrate if using deoxycholic acid can hurt a developing baby. We don't know if this treatment can cause birth defects or miscarriages. We don't know if Kybella® or the substances that are created in the body when it is broken down appear in human milk. Pregnant women and nursing mothers shouldn't get deoxycholic acid treatments.

Drug Interactions:

We don't know if deoxycholic acid reacts with other drugs in the body.

Long-Term Effects:

Deoxycholic acid injections cannot permanently fix a double chin. Your double chin may come back over time. You will also see other changes to your face over time. This may be because of natural processes that have nothing to do with your Kybella® treatment. These changes come from aging, weight loss or gain, sun exposure, or other factors. Deoxycholic acid treatments don't stop you from aging. To keep looking the way you want to, you may need surgery or other treatments in the future.

Additional Treatment:

Many things can affect the results of your deoxycholic acid injections. These can be after treatment or over time. Even though the risks and problems described here are rare, they may happen. Other problems and risks can occur, but these are even less common. If you have these problems after your procedure, you may need more treatments, including surgery. Although most people have good results, there is no guarantee for the results.

DISCLAIMER

Informed consent documents give you information about a procedure you are considering. These documents explain the risks of that procedure. They also discuss other treatment options, including not having surgery. This document is made after a full review of scientific literature and clinical practices. They describe a range of common risks and other forms of management of a disease.
However, informed consent documents can't cover everything. Your plastic surgeon may give you more or different information. This may be based on the facts of your case.

Informed consent documents are not meant to define or serve as the standard of medical care. Standards of medical care are determined based on the facts involved in an individual case. They may change with advances in science and technology. They can also change with the way doctors practice medicine.

 _____ **Patient Initials**
©2020 American Society of Plastic Surgeons®

This form is for reference purposes only. It is a general guideline and not a statement of standard of care. Rather, this form should be edited and amended to reflect policy requirements of your practice site(s), CMS and Joint Commission requirements, if applicable, and legal requirements of your individual states. The ASPS does not certify that this form, or any modified version of this form, meets the requirements to obtain informed consent for this procedure in the jurisdiction of your practice.

It is important that you read the above information carefully and get all your questions answered before signing the consent agreement on the next page.

 _____ **Patient Initials**

©2020 American Society of Plastic Surgeons®

This form is for reference purposes only. It is a general guideline and not a statement of standard of care. Rather, this form should be edited and amended to reflect policy requirements of your practice site(s), CMS and Joint Commission requirements, if applicable, and legal requirements of your individual states. The ASPS does not certify that this form, or any modified version of this form, meets the requirements to obtain informed consent for this procedure in the jurisdiction of your practice.

CONSENT FOR PROCEDURE OR TREATMENT

1. I permit Dr. Thomas Jeneby and the doctor's assistants to give the **Kybella® – Deoxycholic Acid Injection.**
2. I got the information sheet on **Kybella® – Deoxycholic Acid Injection.**
3. I understand that, during the procedure, an unexpected situation may require a different medical procedure than the procedure listed above. I permit the doctor listed above, the assistants, and/or designees to provide any treatment(s) that my doctor thinks are needed or helpful. My permission includes all treatments that my doctor does not plan to do at the start of the procedure.
4. I understand what my surgeon can and cannot do. I understand that no warranties or guarantees have been hinted at or stated outright about the outcome of the procedure. I have explained my goals. I understand which outcomes are realistic and which are not. All my questions have been answered. I understand the procedure's risks. I am aware of other risks and possible issues, benefits, and options. I understand and choose to have the procedure.
5. I agree to the anesthetics and medications that are needed or helpful. I understand that all types of anesthesia have risks and may result in complications, injury, and even death.
6. I am aware of the serious risks to my health when blood products are used. I agree to my doctor using them if my doctor, assistants, and/or designees think they are needed or helpful.
7. I agree to the disposal of any tissue, medical devices, or body parts taken out during or after the procedure. I also agree to any additional surgeries or treatments that are needed or helpful.
8. I agree to have parts of my body photographed or televised appropriately before, during, and after the procedure for medical, scientific, or educational reasons, if the pictures do not reveal my identity.
9. For medical education, I agree that onlookers can be in the operating room.
10. I permit my Social Security Number to be given to the right agencies for legal reasons and medical device registration, when necessary.
11. I agree to the charges for this procedure. I understand that the doctor's charges are separate from the charges for the hospital and the anesthesia. I understand that there may be more charges if more procedures or treatments are needed or helpful. I agree to those charges, if any.
12. I understand that not having the procedure is an option and that I can opt out of having the procedure.
13. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE PROCEDURE TO BE PERFORMED
    b. THERE MAY BE OTHER SURGERIES OR TREATMENT OPTIONS
    c. THERE ARE RISKS TO THE PROCEDURE

I CONSENT TO THE PROCEDURE AND THE ITEMS THAT ARE LISTED ABOVE (1-13).
I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

_____

Patient or Person Authorized to Sign for Patient Date/Time

_____

Witness Date/Time

_____ Patient Initials

©2020 American Society of Plastic Surgeons®