Why my doctor is suggesting treatment with

Prolaryn™ GEL

or

Prolaryn™ PLUS

Not an actual patient.
Your doctor has asked you to read this information because your vocal cords are weak or are not closing properly. Having a weak, breathy voice or hoarseness is a sign that your vocal cords may not be closing all the way. (Your doctor may refer to your vocal cords as “vocal folds.”) The gap between the folds (see illustration below) may make it more difficult to speak or make your voice sound raspy. It can also allow food or liquids to accidentally enter your airway when swallowing.

**Why is my doctor suggesting treatment?**

Your doctor has recommended treatment to help your vocal cords close more properly. This may improve the quality of your voice.

**What can my doctor do to help?**

Your treatment can be given in a clinic or a hospital. Depending on your medical history, your doctor may choose to use a local anesthetic (where you are not asleep) or general anesthesia (where you are unconscious, or “asleep”).

You may be asked to not speak for 3 days. Your doctor will probably recommend a follow-up visit to monitor your progress.

**What can I expect during and after treatment?**

Please see Important Safety Information for PROLARYN GEL and PROLARYN PLUS on page 5.
WHAT IS PROLARYN™ GEL?

PROLARYN GEL is a water-based injectable gel that can help “pump up” (augment) your weakened vocal folds—much like you can inflate a flat tire—and allow them to work more effectively.

PROLARYN GEL has a 7-year history of experience. PROLARYN GEL is an injectable implant that resorbs (dissolves) within 3 to 6 months. Your doctor may choose PROLARYN GEL if he or she feels your condition could improve after treatment, or before treating you with longer-acting PROLARYN PLUS.

Indication: PROLARYN GEL is an injectable implant used in the vocal folds to treat vocal fold insufficiency. The gel mixture disappears within 3-6 months and is a temporary implant.

• Injection with PROLARYN GEL augments or bulks up the displaced or damaged vocal fold so that it can improve speaking. If you have serious difficulties with liquids and/or foods reaching your lungs (aspiration) you may be a candidate for immediate injection.

SELECTED IMPORTANT SAFETY INFORMATION

Contraindications:

• You should not be administered PROLARYN GEL if you have any outside objects in your throat or any pain, redness or swelling in the throat due to any throat irritation, injury or infection.

• Before your physician injects PROLARYN GEL, you should tell your doctor if you have an infection, cancer and any medical conditions that may involve your throat or upper respiratory tract.

• You should not be administered PROLARYN GEL if you have been diagnosed with paralysis of the vocal fold on both sides of your throat or if your voice disorders are caused by psychological or emotional causes.
PROLARYN PLUS is a water-based injectable gel that can help “pump up” (augment) your weakened vocal folds—much like you can inflate a flat tire—and allow them to work more effectively. PROLARYN PLUS has more than 10 years’ history of experience and has shown improvements in voice that can last up to 1 year.

In a clinical study, 81% of patients reported moderate improvement in overall voice function after treatment with PROLARYN PLUS.

**Indication:** PROLARYN PLUS is an injectable implant used to treat vocal fold insufficiency.

• Injection with PROLARYN PLUS augments or bulks up the displaced or damaged vocal fold so that it can improve speaking. If you have serious difficulties with liquids and/or foods reaching your lungs (aspiration) you may be a candidate for immediate injection.

**SELECTED IMPORTANT SAFETY INFORMATION**

**Contraindications:**

• You should not be administered PROLARYN PLUS if you have any outside objects in your throat or any pain, redness or swelling in the throat due to any throat irritation, injury or infection.

• Before your physician injects PROLARYN PLUS, you should tell your doctor if you have an infection, cancer and any medical conditions that may involve your throat or upper respiratory tract.

• You should not be administered PROLARYN PLUS if you have been diagnosed with paralysis of the vocal fold on both sides of your throat or if your voice disorders are caused by psychological or emotional causes.

Please read Additional Important Safety Information on page 5.
Warnings and Precautions:

• PROLARYN GEL should be administered by a trained ear, nose and throat doctor who specializes in treatments of the voice box (larynx) such as an otolaryngologist or an experienced head and neck surgeon.

• PROLARYN GEL and PROLARYN PLUS should not be injected into blood vessels. Injection into blood vessels may cause a blockage leading to serious side effects that can be life threatening. Do not over-inject the vocal fold. In extreme cases site rupture may occur if your vocal folds are over-injected by your physician.

• Before you take PROLARYN GEL or PROLARYN PLUS, you should tell your doctor if you have had multiple surgeries as you may not be an appropriate candidate for bulking injection treatment. The product must be injected into healthy tissue to work. The product may not adhere appropriately to scar tissue and injured tissue from previous surgeries.

• PROLARYN GEL and PROLARYN PLUS may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have trouble swallowing or breathing any time after treatment with PROLARYN GEL or PROLARYN PLUS. Treatment with PROLARYN GEL or PROLARYN PLUS can block your airway immediately after treatment and up to 7 days following injection. This can occur from aggressive vocal fold injection, over-injection of the vocal fold or swelling of the throat due to injury of the voice box (larynx) during the injection procedure.

• For PROLARYN PLUS, therapy should be delayed at least 6 months following the onset of vocal fold paralysis and/or until an adequate trial of voice therapy or rehabilitation has been made.

• For PROLARYN PLUS, some injectable implants have been associated with hardening of the tissues at the injection site, movement of particles from the injection site to other parts of body and/or allergic or autoimmune reactions.

• For PROLARYN GEL and PROLARYN PLUS, the injection procedure and the associated surgical instruments used have a small but inherent risk of infection and/or bleeding.

• For PROLARYN PLUS, some injectable implants have been associated with hardening of the tissues at the injection site, movement of particles from the injection site to other parts of body and/or allergic or autoimmune reactions.

Also, tell your doctor if you are pregnant or plan to become pregnant. (It is not known if PROLARYN GEL or PROLARYN PLUS can harm your unborn baby.)

The following adverse events were received from post-marketing surveillance for PROLARYN PLUS: infection, over-injection/under-injection, ineffective treatment, tissue displacement, exposed material, superficial injection, edema, pain, stiffness at injection site and extraction of material.

For full product information, please visit www.PROLARYN.com or call Merz Customer Service at 866-862-1209.
WHO MAKES PROLARYN GEL AND PROLARYN PLUS?

PROLARYN GEL and PROLARYN PLUS are manufactured and sold by Merz Neurosciences (a division of Merz North America, Inc.). Merz Neurosciences is dedicated to addressing the complexities of treating and living with neurological disorders.

For over 100 years, Merz has been constantly reaching for new levels of excellence. As a company, Merz is committed to providing patients with access to safe and effective treatments while also serving as a trusted treatment source to doctors around the world. Merz continues in this tradition of dedication, investing in the future by researching and developing new treatment options.

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