Why my doctor is suggesting treatment with

Prolaryn® injectable implant GEL

OR

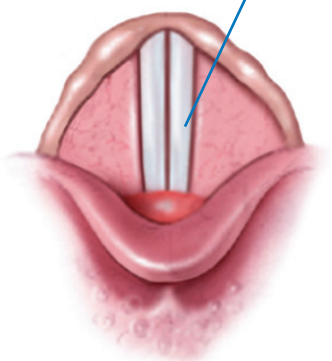
Prolaryn® injectable implant PLUS

Not an actual patient.

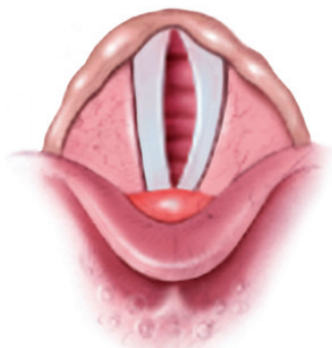
WHY IS MY DOCTOR SUGGESTING TREATMENT?

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.

Not an actual patient.



Normal vocal fold closure



Vocal fold bowing—incomplete closure

What can my doctor do to help?

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

What can I expect during and after treatment?

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").

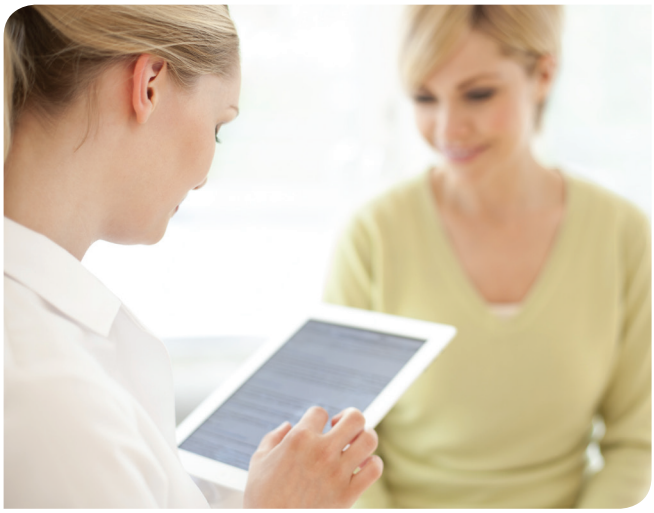
You may be asked to not speak for 3 days. Your doctor will probably recommend a follow-up visit to monitor your progress.

Please see Important Safety Information for PROLARYN GEL and PROLARYN PLUS on pages 5 and 6.

WHAT IS PROLARYN® GEL?

PROLARYN GEL is an injectable, water-based implant 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 more than a 15-year history of treatment. 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.



Not an actual patient.

Indication: Prolaryn GEL is indicated as a resorbable implant material to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. Prolaryn GEL is a temporary implant and resorbs within a period of 3-6 months.

SELECTED IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

- Prolaryn GEL should be used only by trained otolaryngologists or experienced head and neck surgeons.
- Lack of effect is possible. In some cases, initial treatment with Prolaryn GEL may not be effective and additional injections may be indicated.

Please read Additional Important Safety Information on pages 5 and 6.

Prolaryn® injectable implant GEL

WHAT IS PROLARYN® PLUS?

PROLARYN PLUS is an injectable implant that contains biocampatible mineral (calcium hydroxylapatite) in addition to the water-based 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 a 15-year history of treatment and has shown improvements in voice that can last up to 1 year.

These are not actual patients.

In a clinical study, nearly **70%** of patients had "greatly improved" or "significantly improved" voice.[1]

Indication: Prolaryn PLUS is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. Prolaryn PLUS injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication.

SELECTED IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

- Prolaryn PLUS should not be injected into the airway. Confirm placement of needle tip visually before initiating Prolaryn PLUS injection. Prolaryn PLUS should not be injected into organs or other structures that could be damaged by a space occupying implant.
- Prolaryn PLUS therapy should be delayed at least six months following the onset of paralysis and/or until an adequate trial of voice rehabilitation has been made.
- Some injectable implants have been associated with hardening of the tissues at an injection site, migration of particles from an injection site to other parts of the body and/or allergic or autoimmune reactions.

Reference
1. Rosen CA, Simpson CB. Glottic insufficiency: vocal fold paralysis, paresis, and atrophy. In: *Operative Techniques in Laryngology*. Heidelberg, Germany: Springer-Verlag; 2008.

Please read Additional Important Safety Information on pages 5 and 6.

Prolaryn® injectable implant PLUS

Additional Important Safety Information

Warnings and Precautions:

- Prolaryn GEL and Prolaryn PLUS are contraindicated:

  In the presence of foreign bodies, acute inflammation, infection, inadequately controlled malignancy of rapidly advancing disease when these involve the laryngeal or upper respiratory tract.

  In bilateral laryngeal paralysis and vocal disorders of psychogenic or emotional origin.

- Prolaryn GEL and Prolaryn PLUS should not be injected into blood vessels. Injection into blood vessels may cause platelet aggregation, vascular occlusion, infarction, embolic phenomena or hemolysis.
- Safety and effectiveness of Prolaryn GEL and Prolaryn PLUS during pregnancy have not been established.
- Prolaryn GEL and Prolaryn PLUS require viable tissue for effectiveness. Scar tissue and significantly compromised tissue may not coapt appropriately. Patients who have had multiple surgeries may not be appropriate candidates for bulking injection treatment.
- Do not over inject the vocal fold. Prolaryn GEL and Prolaryn PLUS can be easily added in subsequent injections but cannot be easily removed. In extreme cases site rupture could occur.
- Care should be taken with the injection of Prolaryn GEL and Prolaryn PLUS, as with any surgical or implantation procedure, to avoid infection during the injection procedure. If infection occurs and cannot be corrected, if may be necessary to remove the implant.
- Airway obstruction following vocal fold injection can occur immediately or at any time up to seven (7) days following injection. Airway obstruction results from aggressive vocal fold injection, over-injection, or laryngeal edema from trauma and manipulation of the larynx. Airway obstruction can often be prevented by intraoperative and postoperative steroid treatment and by minimizing laryngeal trauma and manipulation.
- The Prolaryn GEL and Prolaryn PLUS injection procedure and the associated instrumentation procedures have small, but inherent risks of infection and/or bleeding like similar otolaryngology procedures. The patient may experience slight discomfort during and following the procedure. The usual precautions associated with otolaryngology procedures, specifically vocal fold injection, should be followed.
- **Do not re-sterilize or store partially used syringes for later use.** Prolaryn GEL and Prolaryn PLUS are supplied sterile and non-pyrogenic in a sealed foil pouch and are intended for single patient use only.
- The foil pouch should be carefully examined to verify that neither the pouch nor the Prolaryn GEL or Prolaryn PLUS syringe has been damaged during shipment. Do not use if the foil pouch is compromised or the syringe has been damaged. Do not use if the syringe end cap or syringe plunger is not in place.
- Use of needles smaller in diameter than 26 gauge may increase the incidence of needle occlusion.

For full safety information including directions for use, storage, and disposal, please visit www.PROLARYN.com or call Merz Customer Solutions at 866-862-1211.

Warnings and Precautions:

Post Market Surveillance:

- Prolaryn GEL has had the following adverse events reported during post market surveillance: dyspnea, pruritus, and cough.
- Prolaryn PLUS has had the following adverse events reported during post market surveillance: infection, over injection/under injection, ineffective treatment, tissue displacement, exposed material, superficial injection, edema, pain, stiffness at injection site, extraction of material, voice changes, dyspnea, airway obstruction, nodule, cough, hypersensitivity reactions including anaphylaxis, urticaria, erythema, facial edema, pruritus, and hives.
- Caution: Rx Only.

For full safety information including directions for use, storage, and disposal, please visit www.PROLARYN.com or call Merz Customer Solutions at 866-862-1211.

Prolaryn® injectable implant GEL

Prolaryn® injectable implant PLUS

MERZ THERAPEUTICS