

Wrinkle Relief: Injectable Cosmetic Fillers

In the quest for youth—or at least a more youthful appearance—women and men are seeking treatments to minimize laugh lines, crow’s feet, and forehead furrows. A popular treatment involves injecting cosmetic wrinkle fillers into the face.

Injectable cosmetic wrinkle fillers are soft tissue fillers approved as medical devices by the Food and Drug Administration (FDA). These devices are injected into the skin to help fill in facial wrinkles, restoring a smoother appearance. Most of these wrinkle fillers are temporary because they are eventually absorbed by the body.

Some people may need more than one injection to achieve the wrinkle-smoothing effect. The effect lasts for about six months or longer.

Successful results depend on

- health of the skin
- skill of the doctor
- type of filler used

Uses

FDA has approved absorbable injectable cosmetic wrinkle fillers for correcting soft tissue contour defects, such as moderate and severe wrinkles and folds. Some absorbable fillers are approved for restoring or correcting the signs of facial fat loss in people with human immunodeficiency virus (HIV).

The only non-absorbable FDA-approved injectable cosmetic wrin-



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kle filler is for correcting facial tissue around the mouth.

FDA-approved cosmetic wrinkle fillers should not be used for

- plumping the lips (lip augmentation)
- increasing breast size (breast augmentation)
- implanting into bone, tendon, ligament, or muscle
- implanting into blood vessels

Filler Materials

Wrinkle fillers are made of various types of materials, and some include a combination of products. Some products also contain lidocaine, which numbs the skin at the injection site.

The materials used in injectable cosmetic wrinkle fillers include

Temporary (absorbable) fillers

- Collagen injections are made of highly purified cow or human collagen. Collagen is a natural protein that is a major component of skin and other tissues in the body.
- Hyaluronic acid gel is a protective lubricating gel, produced naturally by the body, that binds with water to plump the skin.
- Calcium hydroxylapatite is a mineral that is a major component of bone. Calcium hydroxylapatite is a well-matched (biocompatible) material that dissolves in the body (biodegradable) and is implanted in the form of a gel.

- Poly-L-lactic acid (PLLA) is a biodegradable, biocompatible, synthetic material from the alpha-hydroxy-acid family that has been widely used for many years in dissolvable sutures and bone screws.

Permanent (non-absorbable) filler

- Polymethylmethacrylate beads (PMMA microspheres) are tiny round, smooth plastic particles that have been tested to be biocompatible. They are not absorbed by the body.

Risks

Getting injected with cosmetic wrinkle fillers is an elective procedure. As with any medical procedure, it poses risks.

Possible side effects include

- infection
- bruising
- redness
- swelling
- pain
- tenderness
- itching and rash
- raised bumps of skin (nodules or granulomas) that may need to be surgically removed
- death of skin, which may cause disfigurement, if the cosmetic wrinkle filler is injected and blocks a blood vessel
- sore (abscess) at the injection site
- wrinkle filler that breaks through the skin
- open or draining wounds
- blurred vision and flu-like symptoms
- increased allergic reaction that may lead to a severe allergic reaction (anaphylactic shock) that requires emergency medical help. (Your doctor may request a pre-treatment allergy test to determine if you are allergic to the filler.)

Most side effects occur shortly after injection and go away within seven days. In some cases, side effects may emerge weeks, months, or years later.

A non-absorbable filler may cause long-term side effects.

You should not use cosmetic wrinkle fillers if any of the following applies to you:

- severe allergies marked by a history of anaphylactic shock
- allergy to cow collagen or eggs
- allergy to lidocaine
- inflamed or infected skin
- prone to form excessive scarring (keloid) or thick scarring (hypertrophic scars)
- bleeding disorder
- active inflammatory condition (cysts, pimples, rashes or hives) or infection; you should postpone treatment until the condition is controlled.

Tips for Consumers

Before deciding to get injected with a cosmetic wrinkle filler:

- Be aware that the safety of these products is unknown for use in pregnant or breastfeeding women or in patients under 18 years of age.
- Be aware that the safety is unknown when these products are used with Botox or other wrinkle therapies.

What About Botox?

Botox Cosmetic is an injectable drug, but it is not a wrinkle filler. Instead of filling the wrinkle, it keeps muscles from tightening so the wrinkles don't show as much. FDA has approved Botox Cosmetic only to treat wrinkles between the eyebrows.

For More Information

Get the Facts: Botox
www.fda.gov/womens/getthefacts/botox.html

Adverse Reactions Linked to Botox

www.fda.gov/consumer/updates/botox020808.html

- Be aware that the safety of these fillers has only been studied when used in the face.
- Know the type of product that will be injected and all of its possible side effects.
- Discuss fillers with a doctor who can refer you to a specialist in the fields of dermatology and aesthetic plastic surgery.
- Select a doctor who is trained to do the procedure. (You may want to contact the American Academy of Dermatology at www.aad.org or the American Society for Aesthetic Plastic Surgery at www.surgery.org.)
- Have realistic expectations about the benefits you want to achieve and discuss them with your doctor.

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For More Information

Medical Device Approvals: Wrinkle Fillers
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/consumer/index.cfm?topic=1038

Laser Facts: Wrinkle Treatment
www.fda.gov/cdrh/consumer/laserfacts.html#2

Your Guide to Reporting Problems to FDA
www.fda.gov/consumer/updates/reporting_guide061008.html