



# IT'S YOUR HEALTH

## Injectable Cosmetic Treatments

### The Issue

Many Canadians are choosing injectable cosmetic treatments to reduce facial wrinkles and attempt to restore their skin to a smoother appearance.

However, consumers should be aware of the potential for [adverse reactions](#) that are possible with the use of these products.

- sagging, due to the loss of underlying tissue volume
- skin growths and liver spots

[Smoking](#) and hereditary factors can also contribute to the skin conditions above.

Women and men are increasingly seeking out medical and/or cosmetic treatments to attempt to correct or reduce signs of aging. Treatment options range from surgical procedures (facelift, eye lift, etc) to skin rejuvenation treatments such as laser resurfacing, microdermabrasion and chemical peel. Injectable dermal fillers and [Botox® Cosmetic injections](#) have also become increasingly popular treatments.

### Injectable dermal fillers

There are four basic materials used in dermal fillers: autologous fat injections, collagen products, hyaluronic acid products and injections of a carrier material containing microspheres of another biocompatible material (e.g., polymethylmethacrylate or PMMA for short). Be sure to talk to your health care provider when deciding what the most appropriate options are for your situation.

[Hyaluronic acid \(HA\)](#) products are the most commonly used dermal fillers in

### Background

Just like other parts of our bodies, skin ages over time. Excessive occupational and recreational [sun exposure](#) generally causes the most damage to our skin. This kind of exposure can result in:

- wrinkles (either fine surface lines or deep furrows)
- dryness



Canada. There are currently over 30 dermal fillers containing HA licensed for sale in Canada. The effects of HA dermal fillers can last from six months to a year or more, though they are dependent on factors such as:

- the age of the skin
- the severity of the facial defect or the size of the area requiring corrective measures
- the specific type of cosmetic dermal filler being used

### **Botox® Cosmetic injections**

**Botox® Cosmetic** (Botulinum Toxin Type A) is a protein complex produced by the bacterium *Clostridium botulinum*, which contains the same toxin that causes food poisoning (botulism). Botox injections are used for the treatment of various neurological disorders and Botox® Cosmetic is used for cosmetic purposes. In cosmetic use, small injected doses block the ability of underlying facial muscles to contract; this is designed to reduce existing wrinkles on the face. The effects of Botox® Cosmetic treatments generally last anywhere from three to four months.

## **Health Effects**

Anyone considering an injectable cosmetic procedure should always consult a medical professional who has experience in such procedures. Patients should be aware of all the potential risks and benefits of a procedure before obtaining treatment.

### **Injectable dermal fillers**

Dermal fillers are popular and widely used. Both health professionals and consumers should be aware of reported adverse reactions listed on the product labels. These are some of the adverse reaction reports that

Health Canada has received for dermal fillers:

- pain
- bruising
- redness
- swelling or edema
- nodules (raised bumps)
- abscesses (sores)
- infection
- skin discoloration or hyper-pigmentation
- allergic reaction
- improper placement of the material



Many of these adverse reactions are generally temporary, but some could last several months and may require additional treatment and/or procedures to correct. Some of the procedures used to correct an adverse reaction may lead to scars and other skin reactions. A few dermal fillers are intended to be permanently inserted at the site of injection. Since the polymethylmethacrylate (PMMA) microparticles used in these dermal fillers are intended to be permanent, the treatment of potential side effects from these injections is more difficult and surgical removal may be the only solution.

### **Botox® Cosmetic injections**

Complications can arise if Botox® Cosmetic is injected incorrectly. Incorrect injections in the forehead or

around the eyes can result in droopy eyelid muscles (ptosis); too much injected into the neck can cause muscle weakness and swallowing difficulties. Other adverse reactions may include the following signs and symptoms:

- pain/bruising at the injection site
- headache, face pain, eye swelling
- skin rash/allergic reaction
- local muscle weakness/paralysis of the face
- irregular heart beat/chest pain
- malaise (feeling generally unwell)

These [adverse reactions](#) are generally temporary, but could last several months.

A rare but serious reaction to Botox injection is the possibility of the toxin spreading to other parts of the body. This adverse reaction has mainly been associated with non-cosmetic use. These reactions may include the following signs and symptoms:

- muscle weakness away from the injection site
- pneumonia
- swallowing difficulties
- difficulty speaking
- difficulty breathing

If you are using Botox® Cosmetic and experience any of these signs and symptoms, seek immediate medical care. For more information see the [Need More Info](#) section below.

## **Minimizing Your Risks**

Only you can decide what level of risk is acceptable; all medical procedures come with risks.

### **Injectable dermal fillers**

To help minimize the risks associated with cosmetic dermal fillers, avoid or



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postpone treatment if you have any of the following:

- a history of **severe allergies** marked by **anaphylactic shock**
- an allergy to collagen, eggs, or lidocaine
- inflamed or infected skin
- a bleeding disorder
- an active case of cysts, pimples, rashes or hives
- tendency to excessive scarring, such as keloids



Some injectable products are not recommended for lips.

## **Botox® Cosmetic injections**

Botox® Cosmetic injections should only be given by a qualified health care provider, no more frequently than every two months (according to the Canadian product monograph (CPM)). If you are using Botox® Cosmetic products, you

should seek immediate medical care if swallowing, speech, or breathing difficulties arise.

It is important to consult your doctor to learn how Botox® Cosmetic injections and injectable dermal fillers could interact with other injectable cosmetic products, cosmetic procedures or medications that you might be taking for other conditions. Speak with your doctor about possible adverse reactions, and ensure you are working with a medical professional who is trained to do the procedure. It is important to follow the Instruction for Use (IFU) or the Canadian Product Monograph (CPM) of any product and pay close attention to the warnings and contraindications sections. Use these injectable cosmetic treatments with extreme caution if you have a history of:

- underlying neurological disorders
- swallowing difficulties
- breathing problems

Do not obtain injectable cosmetic treatments if you have either of the following:

- inflamed or infected skin
- hypersensitivity to any ingredient in the treatment product

## **Health Canada's Role**

**Health Canada** is a leader and an active partner when it comes to protecting the

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health of Canadians. It takes an integrated approach to managing the risks and benefits of health products in the following ways:

- Minimizes health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products
- Promotes conditions that enable Canadians to make healthy choices
- Provides Canadians with information to make informed decisions about their health

*Vj g'Hqqf "c'pf 'F'twi u'Cev* and its associated Regulations authorize Health Canada to regulate the safety, efficacy and quality of health products such as [drugs](#) and [medical devices](#). As part of this work, Health Canada conducts post market surveillance on all marketed health products. Health Canada also monitors research on interactions between drugs, medical devices, [natural health](#), and [food products](#), and communicates information to health professionals and consumers about the risk of potential interactions. Manufacturers are required to provide Health Canada with reports of serious adverse reactions for health products they sell in Canada. Consumers and health professionals are also encouraged to report adverse reactions by telephone, by fax, by mail or online via the [Ogf Ghlgev Ecpcfc](#) website. Adverse reactions related to medical devices can be reported to the [Health Products and Food Branch Inspectorate](#) toll-free hotline at 1-800-267-9675.

## Need More Info?

- To report an adverse reaction (side effect) related to a Botox® Cosmetic injection visit the [Ogf Ghlgev Ecpcfc](#) website at : [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Report any complaints or concerns about injectable dermal fillers, or any other medical devices, to Health Canada through a toll-free hotline at 1-800-267-9675 or go to the [Health Product and Food Branch Inspectorate consumer complaint](#) web section at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-44\\_consumer\\_complaint-plainte\\_consommateur-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-44_consumer_complaint-plainte_consommateur-eng.php)

For more information on injectable cosmetic treatments visit:

- Canadian Adverse Reaction Newsletter article - [Cf xgtug kpekf gpw'y kj 'kplgew drg j {cmt qple "cekf 'f gto cil krgtu](#) at: [http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei\\_v20n3-eng.php#adv](http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei_v20n3-eng.php#adv)
- Canadian Adverse Reaction Newsletter article - [Dqwrkpw wqzkp "v'rg'C \\*DqvqzI +c'pf 'f kncpv wqzkp "urt gcf](#) at: [http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei\\_v18n4-eng.php#1](http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei_v18n4-eng.php#1)
- Health Canada letter to health care professionals on [Additional safety information related to Botox®/Botox cosmetic®](#) at: [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/medeff/botox\\_hpc-cps-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/botox_hpc-cps-eng.pdf)

- Health Canada advisory on [New Safety Information Regarding Botox and Botox Cosmetic Products](#) at: [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/\\_2009/2009\\_02-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_02-eng.php)
- [Therapeutic Products Directorate](#), at: [www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php)
- [Marketed Health Products Directorate](#), at: [www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/mhpd-dpsc/index-eng.php](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/mhpd-dpsc/index-eng.php)
- [Canadian Society of Plastic Surgeons](#), at: <http://www.plasticsurgery.ca/>
- [Canadian Society for Aesthetic \(Cosmetic\) Plastic Surgery \(CSAPS\) Ancillary Procedures](#) page at: [http://csaps.ca/index.php?option=com\\_content&task=category&sectionid=1&id=19&Itemid=74](http://csaps.ca/index.php?option=com_content&task=category&sectionid=1&id=19&Itemid=74)
- For safety information about food, health and consumer products visit the [Safe Consumers](#) website at: [www.health.gc.ca/consumer](http://www.health.gc.ca/consumer)
- For additional articles on health and safety issues go to the [K'u' qwt 'J gcnj](#) web section at [www.health.gc.ca/iyh](http://www.health.gc.ca/iyh)

You can also call toll-free at 1-866-225-0709 or TTY at 1-800-267-1245