

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrBELKYRA®

Deoxycholic acid injection

Read this carefully before you start using **BELKYRA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BELKYRA**.

What is BELKYRA used for?

BELKYRA is an injectable prescription medicine used in adults to improve the appearance and profile of moderate to severe amounts of fat under the chin. BELKYRA is only for use in a specific area under the chin and not for anywhere else on your body. BELKYRA is only to be administered by a healthcare professional who has been specially trained in the use of the product.

How does BELKYRA work?

BELKYRA contains the active substance deoxycholic acid. Deoxycholic acid is produced naturally in your body to help in the digestion of fats. BELKYRA breaks down fat cells when injected into the fat beneath the chin.

What are the ingredients in BELKYRA?

Medicinal ingredients: Deoxycholic acid.

Non-medicinal ingredients: Benzyl alcohol (preservative), dibasic sodium phosphate, hydrochloric acid, sodium chloride, sodium hydroxide, water for injection.

BELKYRA comes in the following dosage forms:

10 mg/mL solution for injection.

Do not use BELKYRA if:

- are allergic to deoxycholic acid or any of the non-medicinal ingredients in the formulation
- have an infection in your chin or neck area where the product will be injected

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BELKYRA. Talk about any health conditions or problems you may have, including if you:

- have had, or plan to have, plastic surgery on your face, neck or chin, or if you have had other cosmetic treatments such as liposuction or neurotoxins (drugs sometimes used in the neck for cosmetic uses such as wrinkling or other medical reasons) in these areas
- have, or have had, medical conditions in, on or near the neck
- have difficulty swallowing
- are pregnant or plan to become pregnant. It is not known if BELKYRA can harm your unborn baby.
- are breast-feeding or plan to breast-feed as BELKYRA may be found in breast milk
- have any redness, swelling, pain or hard lumps in the area under the chin
- have any medical condition (including high blood pressure, heart problems, coagulation (blood clotting) disorder or circulation problems, diabetes, lupus, have a compromised/weakened immune

system, kidney problems, liver problems, or thyroid problems)

- have a history of skin darkening or lightening with medication
- are taking corticosteroids used to treat joint pain and swelling
- are younger than 18 years of age or over 65 years of age

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Other warnings you should know about:

Injection site problems:

BELKYRA can cause **injection site problems** like open sores (ulcers), tissue damage and death (necrosis), allergic reaction (hypersensitivity), excessive bleeding (hemorrhage) and infections that may require medical and/or surgical treatment. Your healthcare professional might need to treat these problems. See the “Serious side effects and what to do about them” table, below, for more information on these and other serious side effects.

How to take BELKYRA:

Your healthcare professional will inject BELKYRA into the treatment area under your chin. Each treatment session will be scheduled at least 1 month apart until results are achieved for a maximum of 6 treatments. Your healthcare professional will determine how many treatments you need.

Usual dose:

Your healthcare professional will inject small amounts of BELKYRA in several locations in your treatment area. Your healthcare professional will determine how many injections you need based on the amount of fat you have under your chin. You will receive multiple injections per treatment session. The total number of injections and treatment sessions needed to achieve a satisfactory response depends upon the individual.

Overdose:

If you think you, or a person you are caring for, have taken too much BELKYRA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a treatment, you can resume your treatment at anytime if each treatment is at least 1 month apart. Your healthcare professional will determine when you can resume treatment.

What are possible side effects from using BELKYRA?

These are not all the possible side effects you may feel after treatment with BELKYRA. If you experience any side effects not listed here, contact your healthcare professional. Please also see WARNINGS AND PRECAUTIONS section of the Product Monograph.

You may experience pain during the injection procedure. Your pain may last for several days after treatment. In the treatment area, you may also have hair loss, bruising, swelling, numbness, redness, tingling or itchiness, and a sensation of warmth. You may experience a sensation of hardness across the treatment area or in small areas within the treatment area. Some patients reported skin colour

changes, headaches and / or nausea after receiving treatment. You may experience scarring at the injection site after receiving treatment.

| Serious side effects and what to do about them | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------------------|--------------------------------------------------------|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| VERY COMMON | | | |
| Injection site bruising | ✓ | | |
| COMMON | | | |
| Nerve injury (symptoms like uneven smile after treatment) | | ✓ | |
| Trouble swallowing | | ✓ | |
| Low blood pressure immediately following treatment (symptoms like dizziness, fainting, light-headedness) | | ✓ | |
| High blood pressure (symptoms like headache, vision problems, irregular heartbeat) | | ✓ | |
| UNCOMMON | | | |
| Open sore in the treatment area | | ✓ | |
| Injection site problems: <ul style="list-style-type: none"> • open sores (ulcers), damage and tissue death (necrosis) around the injection site • allergic reaction (hypersensitivity) • excessive bleeding (injection site hemorrhage) • injection site infection, including cellulitis and abscess: swollen, red area of skin feels hot and tender | | ✓ | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

BELKYRA should be stored at room temperature (15 to 30°C).

Keep out of reach and sight of children.

If you want more information about BELKYRA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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