

BELKYRA®

10 mg/mL (Bel-ky-ra)

deoxycholic acid solution for injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about BELKYRA® injection.

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Make sure you understand the risks and benefits of BELKYRA® injection.

If you have any concerns about using this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

WHAT BELKYRA® INJECTION IS USED FOR

BELKYRA® is an injectable prescription medicine that contains deoxycholic acid as the active ingredient.

BELKYRA® injection non-surgically reduces fat under the chin, resulting in a more contoured neck profile and jawline.

Ask your doctor if you have any questions about the benefits and risks of this medicine.

This medicine is available only with a doctor's prescription.

BELKYRA® injection is not indicated for use in children or adolescents, younger than 18 years.

BEFORE YOU ARE GIVEN BELKYRA® INJECTION

When you must not be given BELKYRA® injection

This medicine must not be administered if you have an allergy to:

- The active ingredient deoxycholic acid or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

This medicine must not be administered if you have an infection in your chin or neck area where the product will be injected.

If you are not sure whether this medicine is right for you, talk to your doctor.

Before you begin treatment

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- have had or plan to have, plastic surgery on your face, neck or chin or if you have had other

aesthetic treatments such as liposuction or neurotoxins (eg, BOTOX®) (drugs sometimes used in the neck for cosmetic purposes such as to reduce wrinkling or for other medical reasons) in these areas

- have or have had, medical conditions in, on or near the neck, a bleeding disorder or difficulty swallowing.

Tell your doctor if you are pregnant or plan to become pregnant.

It is not known if BELKYRA® injection can harm your unborn baby.

Use in pregnancy is not recommended.

Tell your doctor if you are breast feeding.

The active ingredient in BELKYRA® injection may pass into breast milk. Use while breast feeding is not recommended.

If you have not told your doctor about any of the above, tell him/her before BELKYRA® injection is administered.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with each other. Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

HOW BELKYRA® INJECTION IS GIVEN

A doctor will administer BELKYRA® injection by injecting small amounts of this medicine in several locations in your treatment area approximately every 4 weeks for up to 6 treatments or until the desired result is achieved.

Follow all directions given by your doctor carefully. They may differ from the information contained in this leaflet.

How much is given

Your doctor will determine how many injections you need based on the amount of excess fat you have under your chin. You may need up to 50 injections per treatment session.

How long will BELKYRA® injection be given

The total number of treatment sessions needed to achieve a satisfactory response depends upon the individual. Your doctor will determine how many treatments you need.

No more than 6 treatments can be given. They should be no closer than a minimum of 4 weeks apart.

If you are given too much (overdose)

Immediately telephone your doctor or the **Poisons Information Centre (Australia: telephone 13 11 26; New Zealand: telephone 0800 POISON or 0800 764 766)** or go to Accident and Emergency at the nearest hospital, if you think that you have been given too much BELKYRA® injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE BEING GIVEN BELKYRA® INJECTION

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given BELKYRA® injection.

Tell any other doctors, dentists and pharmacists who treat you that you are being given this medicine.

If you become pregnant while being given this medicine, tell your doctor immediately.

Keep all your doctor's appointments so that your progress can be checked.

Things to be careful of

This medicine is not expected to affect your ability to drive a car or operate machinery.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while BELKYRA® injection is being administered.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Most patients experience mild or moderate pain or discomfort at the time BELKYRA® injection is injected.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- bruising

- pain
- numbness
- swelling
- redness
- tingling
- formation of small areas of hardness
- itching around the treatment area
- high blood pressure

These are mild or moderate side effects of the medicine and are short-lived. Your doctor may ask you to use ice/cold packs, paracetamol, ibuprofen or other ways to reduce side effects.

Tell your doctor as soon as possible if you notice any of the following:

- trouble swallowing
- an uneven smile
- discolouration at the site of injection
- ulcer (open sore) at the site of injection
- unusual hair loss at the site of injection
- taste disturbances
- decreased skin sensation
- damage and tissue cell-death (necrosis) around the injection site
- tingling or reduced sense of touch around the mouth
- scarring around injection site (secondary to skin ulceration or necrosis or injection related)
- injection site infection, including presence of inflammation and pus

The above list includes uncommon side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

The above list includes very serious side effects which may be the sign of an allergic reaction. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER BEING GIVEN BELKYRA® INJECTION

Storage

BELKYRA® injection will be stored by your doctor in a cool dry place, where the temperature stays below 30°C.

PRODUCT DESCRIPTION

What BELKYRA® injection looks like

BELKYRA® injection is a clear, colourless, liquid. It is supplied in single-use 2 mL vials.

Ingredients

Active ingredient:

Deoxycholic acid

Inactive ingredients:

Sodium hydroxide
Dibasic sodium phosphate
Sodium chloride
Water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

AbbVie Pty Ltd
241 O’Riordan Street
Mascot NSW 2020

Australia

Toll free: 1800 252 224 (AU)

AbbVie Limited

6th Floor, 156-158 Victoria St
Wellington, 6011

New Zealand

Free phone: 0800 659 912 (NZ)

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