

BELKYRA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BELKYRA® injection?

BELKYRA® injection contains the active ingredient deoxycholic acid. BELKYRA® injection is used to reduce the fat under the chin, without surgery, resulting in a more contoured neck profile and jawline.

For more information, see Section [1. Why am I using BELKYRA® injection?](#) in the full CMI.

2. What should I know before I use BELKYRA® injection?

Check the list of ingredients at the end of the CMI. Do not use BELKYRA® injection if you have ever had an allergic reaction to any of them.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use BELKYRA® injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BELKYRA® injection and affect how it works, or BELKYRA® injection may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is BELKYRA® injection used?

- BELKYRA® is injected under the skin
- The number of injections and treatment sessions you receive is calculated by your doctor based on your specific needs
- BELKYRA® can only be injected by a suitably qualified doctor.

More instructions can be found in Section [4. How is BELKYRA injection used?](#) in the full CMI.

5. What should I know while using BELKYRA® injection?

| | |
|-----------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are |
|-----------------------------|---|

| | |
|------------------------------------|---|
| | <p>using BELKYRA® injection</p> <ul style="list-style-type: none"> • Follow all directions given to you by your doctor before, during and after you receive your BELKYRA® injection. |
| Things you should not do | <ul style="list-style-type: none"> • Do not skip any appointments as this may result in a less satisfactory outcome. |
| Driving or using machines | <ul style="list-style-type: none"> • BELKYRA® injection is not expected to affect your ability to drive or use machines. |
| Looking after your medicine | <ul style="list-style-type: none"> • BELKYRA® is an injectable medicine which will only be provided to you by your healthcare practitioner in a clinic setting. |

For more information, see Section [5. What should I know while using BELKYRA® injection?](#) in the full CMI.

6. Are there any side effects?

- The most common reactions include bruising, pain, numbness, swelling, redness, itching around the treatment area, tingling, formation of small areas

of hardness under the skin where BELKYRA® has been injected, high blood pressure. Some serious effects can occur in other parts of the body, including shortness of breath, and difficulty swallowing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

BELKYRA®

Active ingredient: *deoxycholic acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BELKYRA® injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BELKYRA® injection.**

Where to find information in this leaflet:

- [1. Why am I using BELKYRA® injection?](#)
- [2. What should I know before I use BELKYRA® injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is BELKYRA® injection used?](#)
- [5. What should I know while using BELKYRA® injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using BELKYRA® injection?

BELKYRA® injection is a prescription medicine that contains the active ingredient deoxycholic acid.

BELKYRA® injection is used to reduce fat under the chin, without the need for surgery, to result in a more contoured neck profile and jawline.

2. What should I know before I use BELKYRA® injection?

Warnings

Do not use BELKYRA® injection if:

- you are allergic to deoxycholic acid, or any of the ingredients listed at the end of this leaflet.
- You are allergic to 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
- you have an infection in your chin or neck area where BELKYRA® is to be injected.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have had or plan to have plastic surgery on your face, chin, or neck
- have had other aesthetic treatments such as liposuction or neurotoxins (e.g. BOTOX®) (drugs sometimes used in the neck for aesthetic purposes such as to reduce wrinkling or for other medical reasons) in these areas

- have or have had difficulty swallowing
- have or have had, medical conditions in, on or near the neck
- have a bleeding disorder or are taking medicines to prevent clotting of the blood
- are on a diet that restricts sodium (or a salt-reduced diet)
- are not sure whether this medicine is right for you
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

It is not known if BELKYRA® injection can harm your unborn baby. Use in pregnancy is not recommended.

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

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

3. What if I am taking other medicines?

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

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

Some medicines may interfere with BELKYRA® injection and affect how it works.

There is limited information available on the use of BELKYRA® injection with other medicines.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these have the possibility of affecting BELKYRA® injection.

4. How BELKYRA® injection is used?

How much is used

The number of injections you receive is calculated by your doctor based on the amount of excess fat you have under your chin. You may need up to 50 injections per treatment session.

When to use BELKYRA® injection

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.

How BELKYRA® injection is given

A doctor will administer BELKYRA® injection by injecting small amounts of this medicine into 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.

If you forget a dose of BELKYRA® injection

It is important that you receive BELKYRA® injection at regular intervals to ensure the best outcome.

If you forget to attend an appointment, contact your doctor for advice and/or to reschedule.

If you use too much BELKYRA® injection

If you think you or anyone else may have swallowed or accidentally injected BELKYRA®

You should immediately:

- phone the Poisons Information Centre **by calling 13 11 26 in Australia or 0800 POISON or 0800 764 766 in New Zealand)), or**
- contact your doctor, or
- go to Accident and Emergency Department at your nearest hospital.

You should do this even if there appears to be no signs of discomfort or poisoning. You may need urgent medical attention.

5. What should I know while using BELKYRA® injection?

Things you should do

Follow all directions given to you by your doctor before, during and after you receive your BELKYRA® injection.

They may differ from the information contained in this leaflet.

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

Call your doctor straight away if you:

- become pregnant while being treated with BELKYRA® injection
- have problems swallowing at any time following your BELKYRA® injection

Remind any doctor, dentist or pharmacist you visit that you are using BELKYRA® injection.

Things you should not do

Do not skip any appointments as this may result in a less satisfactory outcome.

Driving or using machines

BELKYRA® injection is not expected to affect your ability to drive or use machines.

Looking after your medicine

BELKYRA® is an injectable medicine which will only be provided to you by your healthcare practitioner in a clinic setting.

Your doctor or clinic staff will keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Your doctor or clinic staff will dispose of any unused medicine.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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.

Very Serious side effects

| Very Serious side effects | What to do |
|---|---|
| <p>Body as a whole:</p> <ul style="list-style-type: none">• shortness of breath• wheezing or difficulty breathing• swelling of the face, lips, tongue or other parts of the body | <p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Very Serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● rash, itching or hives on the skin. <p>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.</p> | |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <p>Area of treatment (injection):</p> <ul style="list-style-type: none"> ● discolouration of the skin ● ulcer or open sore ● unusual hair loss | <p>Call your doctor straight away if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● decreased skin sensation ● damage and tissue cell death (necrosis) around the injection site ● scarring (secondary to skin ulceration or necrosis or injection related) ● injection site infection including presence of inflammation and pus <p>Head and neck:</p> <ul style="list-style-type: none"> ● difficulty swallowing ● uneven smile ● decreased skin sensation ● tingling or a reduced sense of touch around the mouth <p>Other:</p> <ul style="list-style-type: none"> ● disturbance of taste. | |

Less serious side effects

| Less serious side effects | What to do |
|--|--|
| <p>Area of treatment (injection):</p> <ul style="list-style-type: none">• bruising• pain• numbness• swelling• redness• tingling• formation of small areas of hardness• itching• lump <p>Body as a whole:</p> <ul style="list-style-type: none">• high blood pressure | <p>Speak to your doctor if you have any of these less serious side effects and they worry you. 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.</p> |

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems in Australia or to <https://nzphvc.otago.ac.nz/reporting/> in New Zealand. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop using any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription for injection by a suitably qualified doctor.

What BELKYRA® injection contains

| | |
|---|---|
| Active ingredient (main ingredient) | <ul style="list-style-type: none">● deoxycholic acid |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">● dibasic sodium phosphate● sodium chloride● sodium hydroxide● water for injections. |

Do not use this medicine if you are allergic to any of these ingredients.

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

What BELKYRA® injection looks like

BELKYRA® injection is a clear, colourless liquid. It is supplied in 2 mL single-use glass vials. (Aust R 233201).

Who distributes BELKYRA® injection?

BELKYRA® injection is distributed in Australia by:

AbbVie Pty Ltd

241 O’Riordan Street

Mascot NSW 2020

AUSTRALIA Toll free: 1800 252 224 (AU)

BELKYRA® injection is distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington 6011

NEW ZEALAND

Freephone: 0800 659 912 (NZ)

This leaflet was prepared in December 2025.

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