**Package leaflet: Information for the user**

**BELKYRA 10 mg/ml solution for injection**

deoxycholic acid

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


## 1. What BELKYRA is and what it is used for

Belkyra contains the active substance deoxycholic acid. Deoxycholic acid is produced naturally in your body to aid in the digestion of fats.

The medicine is used in adults for the treatment of submental fat (unwanted fat under the chin) when its presence has an important psychological impact for the patient.

Belkyra contains a non-human, non-animal version of deoxycholic acid which is identical to naturally-occuring deoxycholic acid. Belkyra is an injectable medicine given by your doctor or nurse.

## 2. What you need to know before you use BELKYRA

**Do not use BELKYRA:**
- if you are allergic to deoxycholic acid or any of the other ingredients of this medicine (listed in section 6).
- if you have an infection in your chin or neck area where the product will be injected.

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before using Belkyra. Your doctor or nurse will check how well you are before each treatment. Make sure you tell your doctor or nurse about any illness you have before each treatment.
Your doctor or nurse will pay particular attention to the area around your neck because caution is necessary in the case of any diseases or previous surgery (e.g. scarring, liposuction, difficulty swallowing, enlargement of the thyroid gland or lymph glands).

- Temporary nerve injury in the jaw, leading to an uneven smile or facial muscle weakness, can occur.
- Tissue damage around the treatment area (i.e., skin erosion, ulceration, necrosis) can occur. This can result in scarring. If ulceration or necrosis occur, you should never be given treatment with Belkyra again (see section 4).
- Infection around the treatment area can occur and may require additional medical treatment. If redness or pain develops, talk to your doctor, pharmacist, or nurse.

Belkyra should not be used if you are obese or if you are suffering from body dysmorphic disorder (distorted view of how you look).

**Children and adolescents**
This medicine is not indicated for use in children and adolescents.

**Other medicines and BELKYRA**
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

**Pregnancy and breast-feeding**
The effects of this medicine in pregnant and breast-feeding women are not known. As a precaution the use of Belkyra during pregnancy is not recommended.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine.

**Driving and using machines**
Belkyra is not expected to affect your ability to drive a car or operate machinery.

**BELKYRA contains sodium**
This medicine contains 4.23 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0.2% of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How to use BELKYRA

**How BELKYRA is administered**
Belkyra will be given by a doctor, (or if national guidance permits, a healthcare professional under the supervision of a doctor), directly underneath the skin ('subcutaneous use'). Belkyra will be injected in small amounts in several locations in your treatment area, that is the fat tissue directly below the skin in the area under your chin.

Your doctor or nurse may take some measures for the relief of pain before and after the injection.

**Dose**
A doctor will decide how much Belkyra will be administered.

You will receive multiple injections per treatment session. The total number of injections and treatment sessions needed to achieve a satisfactory response depends upon your individual needs and will be decided by the doctor. Treatment can be repeated multiple times but should not exceed 6 treatment sessions; 2 to 4 treatment sessions are usually sufficient. The time between each treatment session should be at least 4 weeks.

**If you have been administered more BELKYRA than you should**
If more Belkyra is given to you than recommended, this can lead to a possible increase of local side effects (see section 4). If this does happen, talk to your doctor or nurse.

Additional information regarding the use and handling by the medical or healthcare professional is given at the end of this leaflet.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Temporary nerve injury in the jaw, leading to an uneven smile or facial muscle weakness, can occur.

- Tissue damage around the treatment area (i.e., skin erosion, ulceration, necrosis) can occur. This can result in scarring.

If you experience any of the above side effects, contact your doctor or nurse immediately.

Following is a list of the **side effects**, which have been observed according to the following frequencies:

**Very common** *(may affect more than 1 in 10 people):*
- Injection site reactions:
  - pain
  - water retention in the tissue (*oedema*) and swelling
  - sensitivity symptoms (*paraesthesia*): loss of sensitivity, reduced sensitivity, numbness, tingling, unusual sensitivity
  - small round area of localized hardness (*nodule*)
  - bruising
  - firmness or thickening of tissue (*induration*)
  - redness of the skin (*erythema*)
  - itching

**Common** *(may affect up to 1 in 10 people):*
- Injection site reactions:
  - bleeding
  - discomfort
  - warmth
  - change of skin colour
- Nerve injury around the jaw
- Skin tightness
- Difficulties in swallowing (*dysphagia*)
- Feeling sick (*nausea*)
- Headache

**Uncommon** *(may affect up to 1 in 100 people):*
- Unusual taste in the mouth (*dysgeusia*)
- Difficulties in speaking (*dysphonia*)
- Injection site reactions:
  - hair loss (*alopecia*)
  - hives (*urticaria*)
  - skin sores (*ulcer*)
  - allergic reaction (*hypersensitivity*)
  - scar

**Not known** *(frequency cannot be estimated from the available data)*:
- Reduced or abnormal sensation in the area of the mouth (e.g. lip, tongue) (hypoaesthesia oral, paraesthesia oral)
- Injection site reaction (see "Warnings and precautions"):
  - reduced sense of touch or altered sensation in the cheek
  - tissue damage and cell-death (necrosis) around the treatment area
  - infection including redness, swelling, or pain (cellulitis) or a pocket of pus (abscess)
- Injury of blood vessels if injected accidentally into artery or vein

Most of the side effects seen got better during the 4-week period between treatments. However, some of the injection site reactions may be present for a longer period.

**Reporting of side effects**
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store BELKYRA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. After opening, an immediate use of the solution for injection is recommended.

Do not use this medicine if you notice any visible particles.

## 6. Contents of the pack and other information

**What BELKYRA contains**
- The active substance is deoxycholic acid.
  1 ml of solution for injection (injection) contains 10 mg deoxycholic acid. 1 vial with 2 ml contains 20 mg deoxycholic acid.
- The other ingredients are water for injection, sodium chloride, sodium hydroxide (for dissolution and pH adjustment), hydrochloric acid (for pH adjustment) and disodium phosphate anhydrous.

**What BELKYRA looks like and contents of the pack**

Belkyra is a clear, colourless and sterile solution for injection.
Pack size:
One carton with 4 vials (Type I glass with a chlorobutyl rubber stopper, aluminium seal and polypropylene flip-top lid).
Each vial contains 2 ml solution for injection.

**Marketing Authorisation Holder**
AbbVie Limited
Citywest Business Campus
Dublin 24
Ireland

**Manufacturer**
Almac Pharma Services, Ltd.
Seagoe Industrial Estate,
Portadown,
Craigavon,
County Armagh, BT63 5QD

United Kingdom

Allergan Pharmaceuticals International Ltd.
Clonshaugh Business & Technology Park,
Dublin 17,
D17 E400,
Ireland

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Austria, Bulgaria, Estonia, Finland, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Spain, Sweden: BELKYRA

Czech Republic, Slovakia: BELKYRA 10 mg/ml

Norway: Belkyra

Slovenia: BELKYRA 10 mg/ml raztopina za injiciranje

**This leaflet was last revised in 04/2023**
**Version 11**

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**The following information is intended for healthcare professionals only:**

The solution for injection should be inspected visually prior to use. Only clear, colourless solutions free of visible particles should be used.

**Posology**

The total volume injected and the number of treatments should be tailored to the individual patient's submental fat distribution and treatment goals.

Inject 0.2 ml (2 mg) per injection site, 1 cm apart. The maximum dose of 10 ml (100 mg equivalent to 50 injections) should not be exceeded in one treatment session.

Up to a maximum of 6 treatment sessions can be performed. Most patients experience improvement in 2 to 4 treatment sessions.The time interval between treatment sessions should be at least 4 weeks.

To improve patient comfort during injection, oral analgesics or NSAIDs, topical and/or injectable local anaesthesia (e.g., lidocaine) and/or cooling using ice gel packs may be applied to the area of injection at the discretion of the healthcare professional.

Method of administration
The product is indicated for subcutaneous administration only.

Belkyra is supplied in ready-to-use, single-use vials. Gently invert the vial several times prior to use. Do not dilute.

Belkyra shall be prepared for injections in the following way:

1. Remove the flip-off cap from the vial and clean the penetrable stopper of the vial with an antiseptic. If the vial, seal, or flip-off cap is damaged, do not use.
2. Attach a large bore sterile needle to a sterile single-use 1 ml syringe.
3. Introduce the large bore sterile needle into the stopper of the vial and draw 1 ml of Belkyra into the 1 ml syringe.

4. Replace the large bore needle with a 30 gauge (or smaller) 0.5-inch needle. Expel any air bubbles in the syringe barrel before injecting the product into the subcutaneous fat.
5. To withdraw remaining contents of the vial, repeat steps 3 and 4.

Belkyra should only be administered by physicians with appropriate qualifications, expertise in the treatment and knowledge of the submental anatomy. Where national guidance permits, Belkyra may be administered by appropriately qualified healthcare professionals, under the supervision of a physician. Safe and effective use of Belkyra depends on appropriate patient selection, which includes knowledge of patient history of prior interventions and their potential to alter the superficial cervical anatomy. Careful consideration should be given to the use of Belkyra in patients with excessive skin laxity, prominent platysmal bands or other conditions for which reduction of submental fat may result in an undesirable outcome.

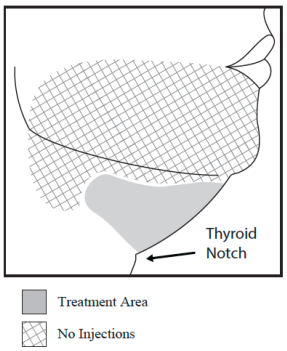
Insert the needle perpendicular to the skin for injections with Belkyra.

Needle placement with respect to the mandible is very important as it reduces the potential for injury to the marginal mandibular nerve, a motor branch of the facial nerve. Injury to the nerve presents as an asymmetrical smile due to paresis of lip depressor muscles.

To avoid injury to the marginal mandibular nerve:

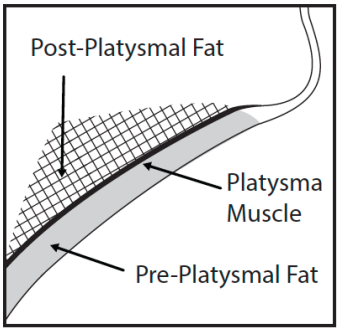
- Do not inject above the inferior border of the mandible.
- Do not inject within a region defined by a 1-1.5 cm line below the inferior border (from the angle of the mandible to the mentum).
- Inject Belkyra only within the target submental fat treatment area (see Figures 1 and 3).

**Figure 1. Avoid the Marginal Mandibular Nerve Area**



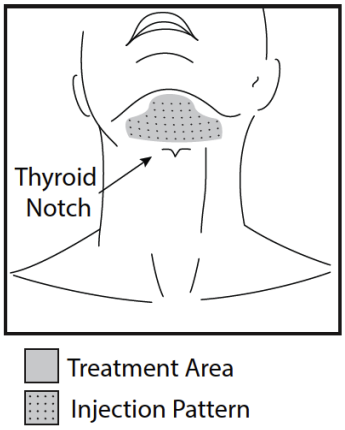

Avoid injection into the platysma. Prior to each treatment session, palpate the submental area to ensure sufficient submental fat and to identify subcutaneous fat between the dermis and platysma (pre-platysmal fat) within the target treatment area (Figure 2).

**Figure 2. Sagittal View of Platysma Area**




Outline the planned treatment area with a surgical pen and apply a 1 $cm^2$ injection grid to mark the injection sites (Figures 2 and 3).

**Figure 3. Treatment Area and Injection Pattern**




Do not inject Belkyra outside the defined parameters.

Each vial is for single patient use only. After use, discard any unused product.