Pr belkyra™
deoxycholic acid injection
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Dosing and ADMINISTRATION GUIDE

AN E.A.S.I. REFERENCE GUIDE FOR **BELKYRA™**

Allergan

STEPS AND *Supplies*

Prbelkyra™
deoxycholic acid injection

E.A.S.I. BELKYRA™ DOSING AND ADMINISTRATION

STEPS	SUPPLIES
EVALUATE submental fullness and identify appropriate **BELKYRA™** patient[1]	
APPLY pre-treatment regimen, mark the treatment zone and apply grid[1]	☑ Topical and/or injectable local anesthesia (e.g., lidocaine)[1] ☑ Topical antiseptic ☑ Surgical pen/pencil ☑ Ruler ☑ Sterile water ☑ Skin marking, 1 cm^2 injection grid ☑ Cotton balls ☑ Gauze pads ☑ Scissors ☑ Cold compress or ice pack
SELECT the **BELKYRA™** dose and prepare syringes[1]	☑ 1 mL syringes ☑ A large-bore needle (e.g., 21G) ☑ 30G (or smaller), 0.5 inch needles ☑ **BELKYRA™** 2 mL vials
INJECT **BELKYRA™** and follow post-treatment recommendations	☑ Gauze ☑ Isopropyl alcohol

IDENTIFY APPROPRIATE BELKYRA™ PATIENT USING P-P-G

PINCH AND PALPATE

- Pinch and palpate the submental area to ensure there is sufficient submental fat for treatment[1]
- Rule out other potential causes of submental fullness (e.g., thyroid abnormality or cervical lymphadenopathy)[1]



PULL

- Pull the submental skin
- Give careful consideration to the use of **BELKYRA™** in patients with excessive skin laxity for which the reduction of submental fat may result in an aesthetically undesirable outcome[1]



GRIMACE

- Have the patient tense the platysma to further define the subcutaneous fat between the dermis and platysma (pre-platysmal fat) within the target treatment area
- Give careful consideration to the use of **BELKYRA™** in patients with prominent platysmal bands for which the reduction of submental fat may result in an aesthetically undesirable outcome[1]



A Apply

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PRE-TREAT

- Clean the lower face and anterior neck with an appropriate topical antiseptic[1]
- Use of ice/cold packs, topical and/or injectable local anesthesia (e.g., lidocaine) are recommended prior to administration to enhance **BELKYRA™** patient comfort[1]



MARK

- Using a surgical pen/pencil, mark the anterior, posterior, and lateral borders of the submental fat compartment[1]
- Mark a "No Treatment Zone" to reduce the potential for injury to the marginal mandibular nerve



APPLY GRID

- Remove and discard clear protective top sheet of skin marking grid from transfer
- Press skin marking grid firmly onto clean, dry skin, with printed grid pattern facing skin
- Thoroughly wet gauze pad with sterile water; press down and wet entire paper backing while maintaining even pressure
- The patient's clothing may be protected using a paper towel
- Wait 15 seconds, then peel off and discard backing
- Alternatively, apply a 1 cm^2 grid pattern using a surgical pen/pencil and ruler[1]
- Apply ice or cold pack for 5 minutes prior to administering **BELKYRA™**[1]





DETERMINE DOSE

- Determine the **BELKYRA™** dose by counting the number of dots within the previously defined target treatment area. Do not count any dots that are outside of the target treatment area.
- Prepare number of syringes based upon calculations below

NUMBER OF DOTS	TOTAL DOSE (mL)*	NUMBER OF 1 mL SYRINGES	NUMBER OF BELKYRA™ VIALS‡
5	1	1	0.5
10	2	2	1
15	3	3	1.5
20	4	4	2
25	5	5	2.5
30	6	6	3
35	7	7	3.5
40	8	8	4
45	9	9	4.5
50	10	10†	5

*In clinical trials, the average total dose was 4 to 6 mL, or between 2 to 3 vials, of **BELKYRA™** administered in a single treatment session.
†No more than 10 mL, or 5 vials, of **BELKYRA™** per treatment session is recommended.[1]
‡Discard unused portion of vials.[1]

PREPARE SYRINGES

- Using a large-bore needle (e.g., 21G), draw 1 mL of **BELKYRA™** from the 2 mL vial into a sterile 1 mL syringe and expel any air bubbles in the syringe barrel[1]
- Replace the large-bore needle with a 30G (or smaller), 0.5 inch needle[1]
- Do not dilute or admix **BELKYRA™**[1]

1 Inject

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INJECT BELKYRA™



- Pinch the pre-platysmal fat between 2 fingers
- Inject perpendicular to the skin until the needle is midway into the underlying pre-platysmal fat[1]
- Inject 0.2 mL of **BELKYRA™** adjacent to each grid marking, or dot, within the target treatment area[1]
- To avoid injury to the marginal mandibular nerve (MMN), do not inject within a region defined by a 1-1.5 cm line below the inferior border of the mandible[1]
- Avoid injection into the platysma or post-platysmal fat. Injections that are too superficial may result in skin ulceration.[1]

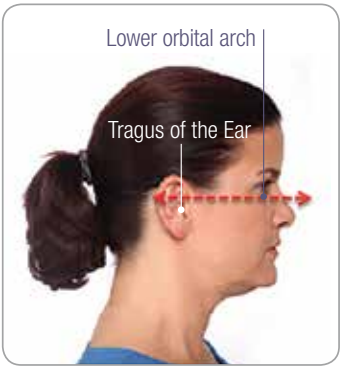
POST-TREATMENT

- Apply ice or cold pack to the treatment area for 5 to 15 minutes[2]
- Remove the grid and markings using cotton dampened with isopropyl alcohol
- Assess smiling and swallowing to screen for MMN injury or dysphagia
- Communicate post-treatment expectations, including the potential for treatment area swelling, bruising, pain, numbness, redness, areas of hardness, tingling or itchiness in the treatment area[1]
- Direct patients to use ice/cold packs and/or oral analgesics (e.g., ibuprofen) to manage side effects as needed[2]
- Encourage the patient to schedule their subsequent **BELKYRA™** treatment session before they leave the office, in no sooner than 1 month. Up to 6 treatments may be administered[1]

Guidance for capturing BEFORE AND AFTER PATIENT PHOTOS

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- Patient photos are important to help assess the **BELKYRA™** treatment process
- To maximize consistency between photos, position the patient in the Frankfort plane, defined as a horizontal plane parallel to the patient's lower orbital arch to the cephalic margin of the tragus of the ear
- Utilize consistent lighting and equipment for all patient photos
- Capture photos in the frontal, right lateral, left lateral, and oblique views before each **BELKYRA™** treatment



Example of a patient positioned in the Frankfort plane

Example patient photos



Frontal view



Lateral view



Oblique view

IMPORTANT SAFETY INFORMATION[1]

Indications and Clinical Use

[PR]**BELKYRA™** deoxycholic acid injection is indicated for: *Improvement in the appearance of moderate to severe convexity or fullness associated with submental fat (SMF) in adults.* **BELKYRA™** is not recommended for use in patients < 18 years of age. **BELKYRA™** is not recommended for pregnant or nursing women. Caution should be exercised in patients > 65 years of age.

Important Limitations of Use

The safe and effective use of **BELKYRA™** for use outside the submental region has not been established and is not recommended.

The safe and effective use of **BELKYRA™** for use in patients with mild or extreme SMF has not been established and is not recommended.

Health professionals administering **BELKYRA™** must receive specialized training before using **BELKYRA™** and understand the relevant submental anatomy and associated neuromuscular structures in the area involved and any alterations to the anatomy due to prior surgical or aesthetic procedures.

Contraindications

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the Product Monograph.
- The presence of infection in the treatment area.

Most Serious Warnings and Precautions

Gastrointestinal: Dysphagia, ranging in duration from 1-81 days (median 3 days) occurred in 2% of **BELKYRA™** patients in clinical trials. **BELKYRA™** is not recommended for patients with a history of dysphagia.

Neurologic: To avoid the potential for nerve injury, **BELKYRA™** should not be injected into or in close proximity to the marginal mandibular branch of the facial nerve.

Skin: Superficial injection may result in skin ulceration. **BELKYRA™** should not be administered in the presence of inflammation or induration at the proposed injection site(s).

Other Relevant Warnings and Precautions

- Thyroid disease/conditions should be ruled out prior to use as a potential contributing cause of submental convexity/fullness (i.e., thyromegaly).
- **BELKYRA™** should be used with caution in patients:
  - with cardiovascular disease and/or impaired circulation (including diabetes mellitus);
  - with renal or hepatic impairment;
  - with bleeding abnormalities or who are currently being treated with antiplatelet or anticoagulant therapy as excessive bleeding or bruising in the treatment area may occur;
  - who are immunosuppressed (including those on chronic steroid therapy);
  - who have had prior surgical or aesthetic treatment of the submental area;
  - using corticosteroids.

For More Information

Please consult the Product Monograph for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece.

The Product Monograph is available by calling us at 1-800-668-6424.

Reference: 1. [PR]**BELKYRA™** Product Monograph. July 23, 2015. **2**. Data on file, Allergan Inc.

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