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# Dosing and Administration Guide

An **E.A.S.I.** reference guide for BELKYRA® (deoxycholic acid) injection



BELKYRA® is indicated for the treatment of moderate to severe convexity or fullness associated with submental fat in adults when the presence of submental fat has a psychological impact for the patient.<sup>1</sup>

 belkyra®

# Steps and Supplies

## E. A. S. I.

### BELKYRA® Dosing and Administration

#### STEPS

#### SUPPLIES

## EVALUATE

submental fullness and identify appropriate BELKYRA® patient<sup>1,3</sup>

## APPLY

pre-treatment regimen, identify the treatment zone<sup>1</sup> and apply skin marking grid<sup>4</sup>

Wait 15 seconds, then peel off and discard backing<sup>4</sup>

- Oral analgesics or NSAIDs, topical and/or injectable local anesthesia (e.g., lidocaine)<sup>1</sup>
- Appropriate topical antiseptic<sup>3</sup>
- Skin marking pen/pencil

- Sterile water<sup>4</sup>
- Skin marking injection grid (1 cm<sup>2</sup>)<sup>4</sup>
- Cotton balls/pad<sup>4</sup>
- Cold compress or ice pack<sup>1,3</sup>

## SELECT

the BELKYRA® dose and prepare syringes<sup>1</sup>

- 1 mL syringes<sup>3,5</sup>
- A large-bore needle<sup>3</sup>

- 30G (or smaller), 0.5 inch needles<sup>3,5</sup>
- BELKYRA® 2 mL vials<sup>1</sup>

## INJECT

BELKYRA® and follow post-treatment recommendations<sup>1</sup>

- Appropriate topical antiseptic<sup>3</sup>

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# Evaluate

## Identify Appropriate BELKYRA® Patients USING P-P-G

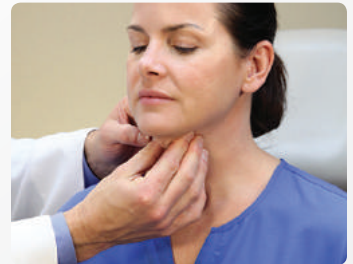
### Pinch and Palpate

- Pinch and palpate the submental area to ensure there is sufficient submental fat for treatment<sup>1,6,7</sup>
- Rule out other potential causes of submental fullness (e.g., thyroid abnormality or cervical lymphadenopathy)<sup>1</sup>



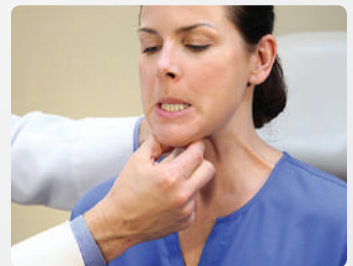
### Pull

- Pull the submental skin<sup>3</sup>
- 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<sup>1,3</sup>



### Grimace

- To isolate the preplatysmal fat, palpate the submental area while patients animate their platysma muscle<sup>3</sup>
- 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<sup>1,3</sup>

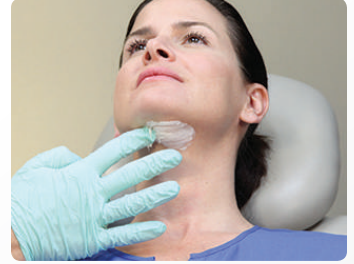


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# Apply

## Pre-treat

- Clean the application area with an appropriate topical antiseptic<sup>4</sup>
- Use of ice/cold packs, topical and/or injectable local anesthesia (e.g., lidocaine) are recommended prior to administration to enhance BELKYRA<sup>®</sup> patient comfort<sup>1</sup>



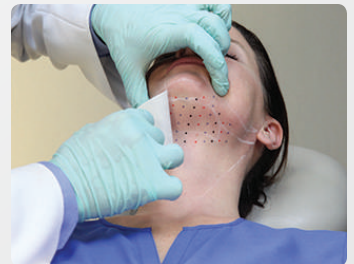
## Mark

- Using a skin marking pen/pencil, mark the anterior, posterior and lateral borders of the submental fat compartment<sup>1</sup>
- Mark a “No Treatment Zone” to reduce the potential for injury to the marginal mandibular nerve<sup>1</sup>



## Apply Grid

- Remove and discard clear protective top sheet of skin marking grid from transfer<sup>4</sup>
- Press skin marking grid firmly onto clean, dry skin, with printed grid pattern facing skin<sup>4</sup>
- Thoroughly wet gauze pad with sterile water; press down and wet entire paper backing while maintaining even pressure<sup>4</sup>
- The patient's clothing may be protected using a paper towel
- Wait 15 seconds, then peel off and discard backing<sup>4</sup>
- Alternatively, apply a 1 cm<sup>2</sup> grid pattern using a skin marking pen/pencil and ruler<sup>1</sup>
- Apply ice or cold pack prior to administering BELKYRA<sup>®1</sup>



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# Select

## Determine Dose

- Determine the BELKYRA<sup>®</sup> 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<sup>3</sup>
- Prepare number of syringes based upon calculations below<sup>\*1</sup>

NUMBER OF DOTS	TOTAL DOSE (mL) <sup>†</sup>	NUMBER OF 1 mL SYRINGES	NUMBER OF BELKYRA <sup>®</sup> VIALS <sup>**</sup>
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 <sup>‡</sup>	5

\* Table provides an example of estimating the number of vials and syringes needed based upon: the injection of 0.2 mL in each injection site being spaced 1-cm apart (2 mg/cm<sup>2</sup>).<sup>1</sup> BELKYRA<sup>®</sup> is supplied in 2 mL vials.<sup>1</sup>

† In clinical trials, the average total dose was 4 to 6 mL, or between 2 to 3 vials, of BELKYRA<sup>®</sup> administered in a single treatment session.

‡ No more than 10 mL, or 5 vials, of BELKYRA<sup>®</sup> per treatment session is recommended.<sup>1</sup>

\*\* Discard unused portion of vials.<sup>1</sup>

## Prepare Syringes

- Using a large-bore needle, draw 1 mL of BELKYRA<sup>®</sup> from the 2 mL vial into a sterile 1 mL syringe and expel any air bubbles in the syringe barrel<sup>3</sup>
- Replace the large-bore needle with a 30G (or smaller), 0.5 inch needle<sup>3</sup>
- Do not dilute BELKYRA<sup>®</sup><sup>1</sup>

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# Inject

## Inject BELKYRA®

- Ensure appropriate topical antisepsis<sup>4</sup>
- Pinch the pre-platysmal fat between 2 fingers<sup>3</sup>
- BELKYRA® injections should be perpendicular to the skin surface until the needle is mid-way into the pre-platysmal subcutaneous fat tissue in the submental area<sup>3</sup>
- Inject 0.2 mL of BELKYRA® adjacent to each grid marking, or dot, within the target treatment area<sup>1</sup>
- 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<sup>1,3</sup>
- Avoid injection into the platysma or post-platysmal fat. Injections that are too superficial may result in skin ulceration<sup>1,3,7</sup>



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## Post-treatment

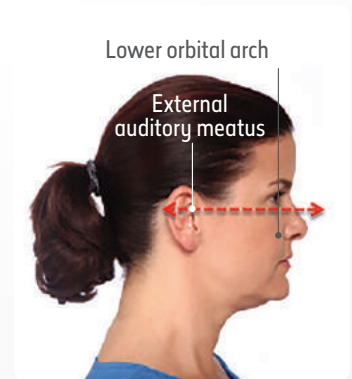
- Apply ice or cold pack to the treatment area for 5 to 15 minutes<sup>5,8</sup>
- Remove the grid and markings using cotton dampened appropriately<sup>3,4</sup>
- Assess smiling and swallowing to screen for MMN injury or dysphagia<sup>3</sup>
- Communicate post-treatment expectations, including the potential to experience varied degrees of local swelling and oedema, bruising, pain, numbness, redness, areas of hardness, tingling or itchiness in the treatment area<sup>3</sup>
- Direct patients to use ice/cold packs and/or oral analgesics as needed<sup>3,5</sup>
- Encourage the patient to schedule their subsequent BELKYRA® treatment session before they leave the office, in no sooner than 1 month.<sup>1</sup> Up to 6 treatments may be administered<sup>1</sup>

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# Guidance for Capturing

## Before and After Patient Photos

- Patient photos are recommended 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 upper margin of each ear canal or external auditory meatus
- Standardized technique, lighting, and equipment for all patient photos is essential for accurate analysis<sup>9</sup>
- Capture photos in the frontal, right lateral, left lateral, and oblique views before each BELKYRA® treatment<sup>9</sup>



EXAMPLE OF A PATIENT POSITIONED IN THE FRANKFORT PLANE

## Example Patient Photos

FRONTAL VIEW



LATERAL VIEW



OBLIQUE VIEW



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**BELKYRA® 10 mg/ml** injektionsvätska, lösning, deoxicholsyra, övriga dermatologiska medel, ATC-kod: D11AX24, Rx. EF. **Indikation:** Behandling av måttlig till svår utbuktning eller utfyllnad kopplad till submentalt fett (s k dubbelhaka) hos vuxna när förekomsten av submentalt fett har en psykologisk inverkan på patienten. **Kontraindikationer, varningar och försiktighet:** Överkänslighet mot deoxicholsyra eller mot något hjälpämne. Förekomst av infektion vid de planerade injektionsställena.

Patienter bör screenas med avseende på andra orsaker till submental utbuktning eller utfyllnad (t.ex. förstoring av sköldkörteln eller lymfkörteln) före användning av BELKYRAS. Får endast administreras subkutant, injicera inte närmare än 1 till 1,5 cm från känsliga anatomiska strukturer, får inte injiceras i eller i nära anslutning till ramus marginalis mandibularis, för att undvika risk för motorisk neuropraxi. Försiktighet ska iakttas för att undvika oavsiktlig intra-dermal eller intramuskulär injektion, undvik injektion i salivkörtlar, tyroideakörtel, lymfknotor och muskulatur, om patienten tidigare har genomgått kirurgisk eller estetiskt behandling i det submentala området, när BELKYRA® administreras i närvaro av inflammation eller förhårdnader vid det tänkta injektionsstället (-ställena) eller hos patienter med symtom på dysfagi. Texten är baserat på produktresumé med godkännandedatum 2016-10-05. För ytterligare information om produkten samt pris se [www.fass.se](http://www.fass.se).

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**References:** 1. BELKYRA® Product resume 161005 2. Ascher B, et al. Efficacy, patient-reported outcomes and safety profile of ATX-101 (deoxycholic acid), an injectable drug for the reduction of unwanted submental fat: results from a phase III, randomized, placebo-controlled study. *JEADV*. 2014; 28:1707-1715. 3. Jones DH, et al. Proper Technique for Administration of ATX-101 (Deoxycholic Acid Injection): Insights from an Injection Practicum and Roundtable Discussion. *Dermatol Surg*. 2016; 42:S275-S281. DOI: 1-1097/DSS.0000000000000875. 4. BELKYRA® Skin Marking Grid Directions for Use. Allergan Inc., 2016. 5. Dover JS, et al. Management of Patient Experience with ATX-101 (Deoxycholic Acid Injection) for Reduction of Submental Fat. *Dermatol Surg*. 2016; 42:S288-S299. DOI: 10.1097/DSS.0000000000000908. 6. Cohen JL, et al. Additional thoughts on the new treatment Kybella. *Semin Cutan Med and Surg*. 2015; 34:138-139. 7. Ascher B, Fellman J and Monheit G. ATX-101 (deoxycholic acid for reduction of submental fat. *Expert Review of Clinical Pharmacology*. 2016; 9(9):1131-1143. DOI: 10.1080/17512433.2016.1215911. Accessed October 20, 2016. 8. BELKYRA® Data on File, INT/0792/2016. 9. Khavkin J and Ellis DAF. Standardized Photography for Skin Surface. *Facial Plast Surg Clin N Am*. 2011; 19:241-246.

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The belkyra logo features a stylized lowercase 'b' in red, followed by the word "belkyra" in a lowercase, blue, sans-serif font. A registered trademark symbol (®) is located at the end of the word.