# AUSTRALIAN PRODUCT INFORMATION
# BELKYRA® (DEOXYCHOLIC ACID)

## 1 NAME OF MEDICINE

Deoxycholic acid

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

BELKYRA® solution for injection contains deoxycholic acid 10 mg/mL

For the full list of excipients, see Section 6.1 List of excipients.

## 3 PHARMACEUTICAL FORM

BELKYRA® (deoxycholic acid) injection is a formulation of synthetically derived deoxycholic acid in a sterile solution for subcutaneous injection. No human or animal-derived materials are used in the manufacture of synthetic deoxycholic acid.

Deoxycholic acid is a white to off-white crystalline powder and is freely soluble in alkaline solutions. The pKa and logP of deoxycholic acid have been determined at 25°C to be 6.0 and 4.1, respectively.

BELKYRA® injection is a clear, colourless liquid essentially free of visible particulates. Each single-use 2 mL vial contains 20 mg (10 mg/mL) of deoxycholic acid formulated in a sterile solution of sodium hydroxide, dibasic sodium phosphate, sodium chloride and water for injections. The formulation is adjusted to pH 8.3 with hydrochloric acid or sodium hydroxide and has a tonicity compatible with that of biological tissues and fluids.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

BELKYRA® (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

### 4.2 Dose and method of administration

**Dosing Considerations**

BELKYRA® injection should be administered by a medical practitioner, who understands the relevant submental anatomy and associated neuromuscular structures and any alterations to the anatomy in a particular individual patient (e.g. due to prior surgical or aesthetic procedures) *(see Section 4.4 Special warnings and precautions for use).*

Screen patients for other potential causes of submental convexity/fullness (e.g. thyromegaly and cervical lymphadenopathy).

Use caution in patients who have had prior surgical or aesthetic treatment of the submental area. Changes in anatomy/landmarks or the presence of scar tissue may impact the ability to safely administer BELKYRA® injection or to obtain the desired aesthetic result.

**Recommended Dose**

BELKYRA® is injected into subcutaneous fat tissue in the submental area using an area-adjusted dose of 2 mg/cm$^2$.

- A single treatment consists of up to a maximum of 50 injections, 0.2 mL each (up to a total of 10 mL), spaced 1 cm apart.
- Up to 6 single treatments may be administered at intervals no less than 1 month apart.

**Administration**

BELKYRA® injection is supplied in vials containing 2 mL of a 10 mg/mL solution and should be clear, colourless and free of particulate matter.

Visually inspect BELKYRA® vials for particulate matter and/or discolouration and discard the vial if the solution is discoloured and/or contains particulate matter.

Gently invert the vial several times prior to use. Do not dilute. After use, discard any remaining solution in the vial. Product is for single use in one patient only.

**Injection Technique**

The safe and effective use of BELKYRA® injection depends on the use of the correct number and locations for injections, proper needle placement and administration techniques (*see Section 4.4 Special warnings and precautions for use)*.

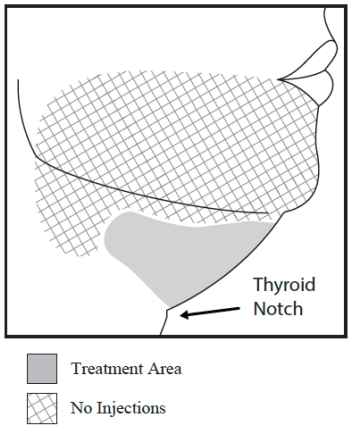
**Avoid injections near the area of the marginal mandibular nerve *(see Section 4.4 Special warnings and precautions for use).***

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 *(see Section 4.4 Special warnings and precautions for use)*.

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).

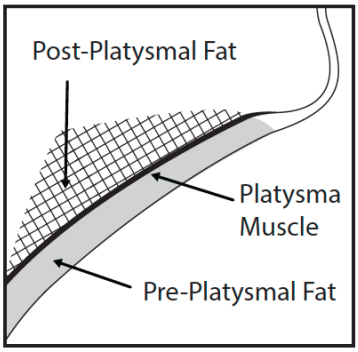
**Figure 1. Avoid the Marginal Mandibular Nerve Area**



**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 (refer to Figure 2). The number of injections and the number of treatments should be tailored to the individual patient's submental fat distribution and treatment goals.

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

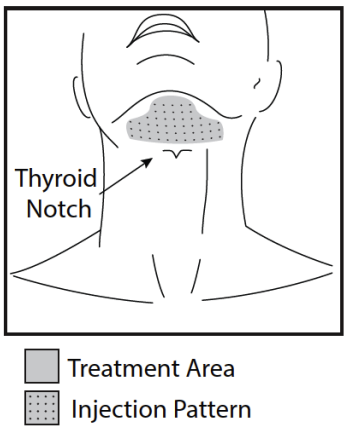



**Injecting into the treatment area**

Use of ice/cold packs, topical and/or injectable local anaesthesia (e.g. lidocaine) may enhance patient comfort.

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

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




**Do not inject BELKYRA® outside the defined parameters *(see Section 4.4 Special warnings and precautions for use)***

- Using a large bore needle, draw 1 mL of BELKYRA® injection into a sterile 1 mL syringe and expel any air bubbles in the syringe barrel.
- Have the patient tense the platysma. Pinch the submental fat and using a 30 gauge (or smaller) 0.5-inch needle, inject 0.2 mL of BELKYRA® into the pre-platysmal fat (see Figure 2) next to each of the marked injection sites by advancing the needle perpendicular to the skin.

- Injections that are too superficial (into the dermis) may result in skin ulceration and necrosis. Do not withdraw the needle from the subcutaneous fat during injection as this could increase the risk of intradermal exposure and potential skin ulceration and necrosis.
- Avoid injecting into the post-platysmal fat by injecting BELKYRA® into fat tissue at the depth of approximately mid-way into the subcutaneous fat layer (refer to Figure 2).
- If at any time resistance is met as the needle is inserted, indicating the possibility of contact with fascial or non-fat tissue, the needle must be withdrawn to an appropriate depth before the injection is administered.
- Avoid injecting into other tissues such as the muscle, salivary glands (including salivary ducts), lymph nodes, arteries or veins.
- Upon needle withdrawal, pressure may be applied to each injection site as necessary to minimise bleeding; an adhesive dressing may be applied.

## 4.3 Contraindications

- BELKYRA® injection is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, *see Section 6.1 List of excipients*.
- BELKYRA® injection is contraindicated in the presence of infection in the treatment area.

## 4.4 Special warnings and precautions for use

### General

To be administered only by subcutaneous route.

Do not inject within 1 cm of vulnerable anatomic structures. Efficacy and safety of BELKYRA® injection has not been established outside the submental fat area. Do not inject in any other area.

Efficacy and safety of BELKYRA® injection in patients with mild or extreme submental fat has not been established and is not recommended.

To achieve the efficacy and safety reported from the pre-market clinical trials, medical practitioners administering BELKYRA® injection must understand the relevant submental anatomy and associated neuromuscular structures; and any alterations to the anatomy in a particular individual patient (e.g. due to prior surgical or aesthetic procedures).

### Marginal mandibular nerve injury

BELKYRA® should not be injected into or in close proximity to the marginal mandibular branch of the facial nerve to avoid the potential for motor neuropraxia, which manifests as an asymmetric smile or facial muscle weakness. The median time to resolution of marginal mandibular nerve injuries, which occurred at an incidence rate of 2.0% in the pre-market clinical trials, was 44 days; range: 1 to 298 days.

### Dysphagia

Difficulty swallowing (dysphagia) occurred in the pre-market clinical trials in the setting of administration site reactions; for example, pain, swelling and induration of the submental

area. The median time to resolution of dysphagia, which occurred at an incidence rate of 1.1% in the pre-market clinical trials, was 3 days; range: 1 to 81 days.

Patients with current or prior history of dysphagia were excluded from clinical trials; avoid the use of BELKYRA® injection in such patients as treatment may exacerbate the condition.

**Injection site haematoma/bruising**

BELKYRA® injection should be used with caution in patients with bleeding abnormalities or who are currently being treated with anti-platelet or anti-coagulant therapy as excessive bleeding or bruising in the treatment area may occur. In pre-market clinical trials, 61% of people treated with BELKYRA® injection experienced injection site bleeding/haematoma.

**Risk of injecting in proximity to vulnerable anatomic structures**

Care should be taken to avoid inadvertent intradermal or intramuscular injection. BELKYRA® should be injected mid-way into the pre-platysmal subcutaneous fat tissue in the submental area. Injections that are too superficial (into the dermis) may result in skin ulceration and necrosis. Do not withdraw the needle from the subcutaneous fat during injection, as this could increase the risk of intradermal exposure and potential skin ulceration and necrosis. Cases of injection site infection have been reported, some of which included cellulitis and abscess requiring additional medical treatment. Consider withholding subsequent treatment with BELKYRA® injection until resolution of injection site ulceration, necrosis or infection.

Avoid injection into salivary glands (including salivary ducts), the thyroid gland, lymph nodes and muscles. Care should be taken to avoid inadvertent injection directly into an artery or vein as it can result in vascular injury.

BELKYRA® injection should not be administered into the periorbital area.

**Pre-existing Conditions/Treatments at or Near the Treatment Area**

Patients should be screened for other potential causes of submental convexity/fullness (e.g. thyromegaly and cervical lymphadenopathy) prior to use of BELKYRA® injection.

Caution should be used when BELKYRA® injection is administered in the presence of inflammation or induration at the proposed injection site(s).

Caution should be used when BELKYRA® injection is administered in patients who have had prior surgical or aesthetic treatment of the submental area. Changes in anatomy/landmarks or the presence of scar tissue may affect the ability to safely administer BELKYRA® injection or to obtain the desired aesthetic result.

Caution should be used in patients with excessive skin laxity, prominent platysmal bands or other conditions for which reduction of submental fat may result in an aesthetically undesirable outcome.

**Controlled sodium diet**

BELKYRA® injection contains 184 micromol (or 4.23 mg) sodium per mL. This should be taken into consideration in patients on a controlled sodium diet.

**Use in the elderly (> 65 years of age)**

The clinical trials with BELKYRA® injection did not include sufficient numbers of subjects over age 65 to determine whether they respond differently than younger subjects; therefore, caution should be exercised with these patients.

**Paediatric use (< 18 years of age)**

Safety and effectiveness in patients below the age of 18 years have not been established and BELKYRA® injection is not intended for use in children or adolescents.

**Effects on laboratory tests**

Interactions with laboratory tests have not been established.

## 4.5 Interactions with other medicines and other forms of interactions

No clinical drug interaction studies have been conducted with BELKYRA® injection. The use of BELKYRA® injection concomitantly with botulinum toxin has not been evaluated.

Results from *in vitro* studies on inhibition and induction of cytochrome P450 (CYP) enzymes and inhibition of uptake and efflux transporters, including those involved in the enterohepatic circulation of bile acids, did not predict a potential for drug-drug interactions with BELKYRA® injection at clinically relevant doses.

## 4.6 Fertility, pregnancy and lactation

**Effects on fertility**

There are no clinical data on fertility.

Deoxycholic acid did not affect general reproductive performance or fertility in male or female rats at subcutaneous doses up to 50 mg/kg once weekly, yielding 5 and 3 times the plasma AUC in subjects at the maximum recommended human dose in the respective sexes.

**Use in pregnancy – Pregnancy Category B1**

Embryofoetal development studies have been performed in rats at doses up to 50 mg/kg and in rabbits at doses up to times 30 mg/kg, administered subcutaneously on alternate days during the period of organogenesis. These doses yielded approximately 2 and 17 times the plasma AUC in subjects at the maximum recommended human dose in the respective species. They have revealed no evidence of harm to the foetus. No adequate and well-controlled studies in pregnant women have been performed. However, because animal reproduction studies are not always predictive of human response, BELKYRA® injection is not recommended for use during pregnancy.

**Use in lactation**

Endogenous deoxycholic acid has not been observed in human milk. Because studies in nursing mothers have not been conducted, BELKYRA® injection is not recommended for use by nursing women.

## 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. It is presumed to be safe to drive and use machines while using BELKYRA® injection.

## 4.8 Adverse effects (Undesirable effects)

### Clinical trial experience

The data described in Table 1 reflects undesirable effects reported for BELKYRA®-treated patients (N = 1118) who were evaluated in the clinical studies that assessed the use of BELKYRA® injection for the treatment of submental fat.

The following side effects have been evaluated in clinical studies with the following frequencies:

- Very common (≥ 1/10)
- Common (≥ 1/100 to <1/10)
- Uncommon (≥ 1/1,000 to <1/100)
- Rare (≥ 1/10,000 to <1/1,000)
- Very rare (<1/10,000)
- Not known (cannot be estimated from the available data).

**Table 1: Adverse Effects Reported in Clinical Trials**

| System Organ Class | Frequency | Adverse Effects |
|---|---|---|
| Nervous system disorders | Common | Headache |
| | Uncommon | Dysgeusia |
| Respiratory, thoracic and mediastinal disorders | Uncommon | Dysphonia |
| Gastrointestinal disorders | Common | Dysphagia, nausea |
| Skin and subcutaneous tissue disorders | Common | Skin tightness |
| General disorders and administration site conditions | Very Common | Injection site: Pain, oedema, swelling, anaesthesia, nodule, haematoma, paraesthesia, induration, erythema, pruritus |
| | Common | Injection site: Haemorrhage, discomfort, warmth, discolouration, bruising |
| | Uncommon | Injection site: Alopecia, urticaria, ulcer, hypersensitivity |
| Injury, poisoning and procedural complications | Common | Injection site nerve injury |
| Vascular disorder | Common | Hypertension |

### Post-marketing experience

The following adverse effects have been identified during post-marketing use of BELKYRA® injection. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made.

**General disorders and administration site conditions:** Injection site conditions such as alopecia in males, hypoaesthesia, ulceration and necrosis, injection site scar (secondary to skin ulceration or necrosis and post-injection scar tissue), injection site infection.

**Immune System Disorders:** Hypersensitivity.

**Nervous System Disorders:** Hypoaesthesia oral and paraesthesia oral.

**Injury, Poisoning and Procedural Complications:** Vascular injury due to inadvertent intravascular injection.

### Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions in Australia at www.tga.gov.au/reporting-problems and in New Zealand at https://nzphvc.otago.ac.nz/reporting.

## 4.9 Overdose

No overdosing with BELKYRA® injection in humans has been reported. Injection of increased volume or decreasing the spacing between injections of BELKYRA® may be expected to increase risk of local adverse effects. Non-treatment area or systemic adverse reactions were infrequent during clinical studies of doses up to 200 mg.

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia) or the National Poisons Centre on 0800 POISON (0800 764766 New Zealand).

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatologicals; ATC code: D11AX

### Mechanism of action

Deoxycholic acid is a cytolytic drug which when injected into localised subcutaneous fat physically disrupts the cell membrane of adipocytes and causes cell lysis. The destruction of adipocytes elicits an expected tissue response in which macrophages are attracted to the area to eliminate cellular debris and lipids, which are then cleared through natural processes. This is followed by the appearance of fibroblasts and observed thickening of fibrous septa, likely due to an increase in total collagen (i.e., neocollagenesis).

### Pharmacodynamics

In clinical dose-ranging trials of submental fat reduction, higher efficacy was observed with BELKYRA® injection dosed at 2 mg/cm$^2$ (based on clinician and patient rating scales, patient-reported outcomes and MRI measurements) compared with BELKYRA® injection dosed at 1 mg/cm$^2$, with little or no difference in safety profile.

In clinical trials, no clinically significant effect of BELKYRA® injection was observed on circulating lipid levels or any other laboratory parameter.

A QT/QTc study was conducted and neither 100 mg BELKYRA® injection nor the supratherapeutic dose of 200 mg BELKYRA® injection demonstrated a propensity to prolong the ECG QT duration in healthy volunteers.

## Clinical trials

### Study demographics and trial design

Two identical Phase 3, randomised, multi-centre, double-blind, placebo-controlled trials of BELKYRA® injection for use in the improvement in the appearance of convexity or fullness associated with submental fat (SMF) were conducted in Canada and the United States as pivotal studies. Two supportive, identical Phase 3 studies of BELKYRA® injection for treatment of convexity or fullness associated with SMF were conducted in the European Union. The pivotal trials enrolled healthy adults (ages 19 to 65, BMI ≤ 40) with moderate or severe SMF (i.e., grade 2 or 3 on 5-point validated grading scales, where 0 = none, 4 = extreme), as judged by both clinician and patient ratings.

In the pivotal studies, subjects received up to six treatments with BELKYRA® injection (N = 515, combined trials) or placebo (N = 504, combined trials) at approximately 4-week intervals. Use of ice/cold packs, topical and/or injectable local anaesthesia was allowed during the clinical trials. Injection volume was 0.2 mL per injection site, spaced 1 cm apart into the submental fat tissue, which is expressed as dose per area as 2 mg/cm$^2$. For each treatment session a maximum of 100 mg (10 mL or up to 50 injections) was permitted over the entire treatment area. The primary efficacy assessments were based on the composite clinician-reported (CR) and patient-reported (PR) ratings of SMF (concurrent improvement reported by both physician and patient) at 12 weeks after final treatment, relative to baseline. The trials employed co-primary endpoints: at least a 1-grade composite improvement and at least a 2-grade composite improvement. As a secondary endpoint, visual and emotional impacts of SMF were evaluated using a 6-question survey (happy, bothered, self-conscious, embarrassed, looking older or overweight in relation to the appearance of their SMF), with each question rated from 0 (not at all) to 10 (extremely/very much). In addition, magnetic resonance imaging (MRI) was performed in a subset of subjects (N = 449, combined trials) to confirm reduction of submental fat.

In these trials, the mean age was 49 years and the mean BMI was 29 kg/m$^2$. Most of the subjects were women (85%) and Caucasian (87%). At baseline, 51% of the subjects had a clinician-rated SMF severity of moderate and 49% had a SMF rating of severe.

In the pre-market clinical trials, BELKYRA® injection was administered by plastic surgeons, dermatologists and a small number of other medical practitioners with extensive experience in administration of aesthetic treatments.

### Pivotal trial results

Both 1-grade and 2-grade reductions in SMF were observed more frequently in the BELKYRA® injection group compared to the placebo group as measured by the composite clinician and patient ratings; 68.2% of BELKYRA®-treated subjects had at least a 1-grade composite Submental Fat Rating Scale (SMFRS) response compared to 20.5% of placebo-treated subjects. Sixteen percent (16.0%) of BELKYRA®-treated subjects had at least a 2-grade composite SMFRS response compared to 1.5% of placebo-treated subjects (refer to Table 2). The individual clinician and patient assessments of response from which the composite response is derived are provided in Figure 4. The impact of SMF on emotional and self-perceived visual attributes showed a significant improvement in the BELKYRA®

injection group compared to the placebo group as shown in Figure 5. BELKYRA®-treated patients dropped 48.6% from a baseline of 7.27 to 3.74, or -3.53, at 12 weeks after the last treatment measured on a scale of 0 (no impact at all) to 10 (extreme impact). Placebo-treated patients dropped 17.3% from a baseline of 7.28 to 6.02, or -1.26, at 12 weeks after the last treatment. Statistically significant improvements in subject satisfaction were observed more frequently in the BELKYRA® injection group compared to the placebo group as measured by the Subject Self Rating of Satisfaction scale. MRI measurements taken to confirm the reduction of submental fat indicate that a greater proportion of BELKYRA®-treated subjects had at least a 10% reduction in submental fat volume as compared to placebo-treated subjects (43% vs 5%, respectively).

**Table 2: Co-Primary Endpoints: > 1-Grade and > 2-Grade Composite Clinician and Patient Response 12 Weeks After Final Treatment**

| **Endpoint** | **ATX-101** (N=514) | **Placebo** (N=508) | **p-value** |
|---|---|---|---|
| 1-Grade Composite Response | 351 (68.2%) | 104 (20.5%) | <0.001 |
| 2-Grade Composite Response | 82 (16%) | 8 (1.5%) | <0.001 |

**Figure 4: Clinician-Reported and Patient-Reported Assessment of Response (SMFRS)**

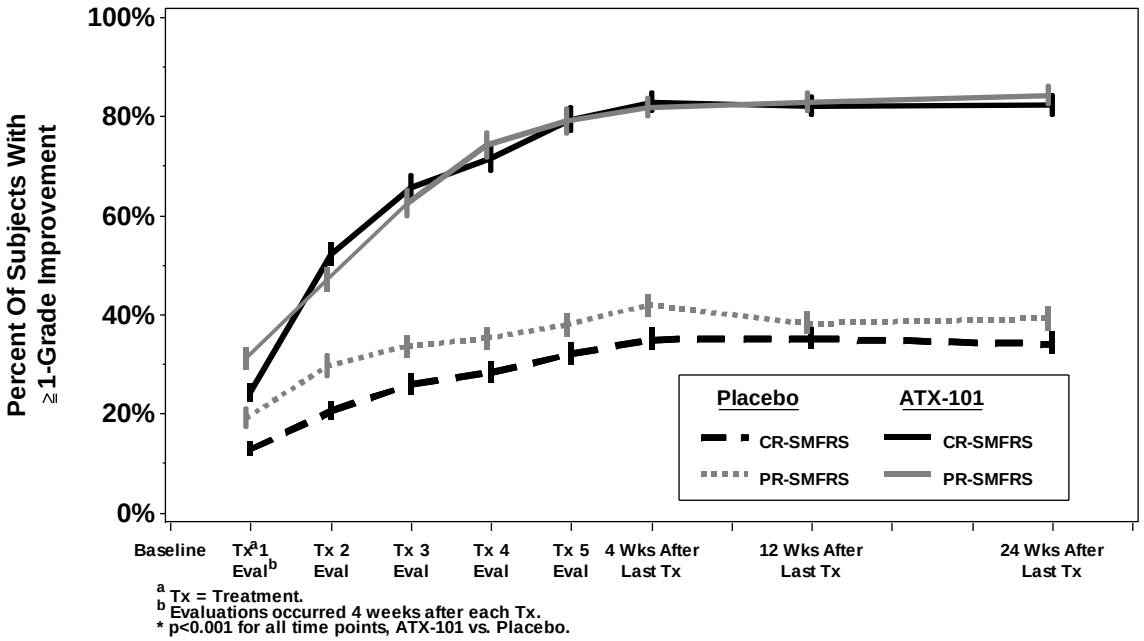
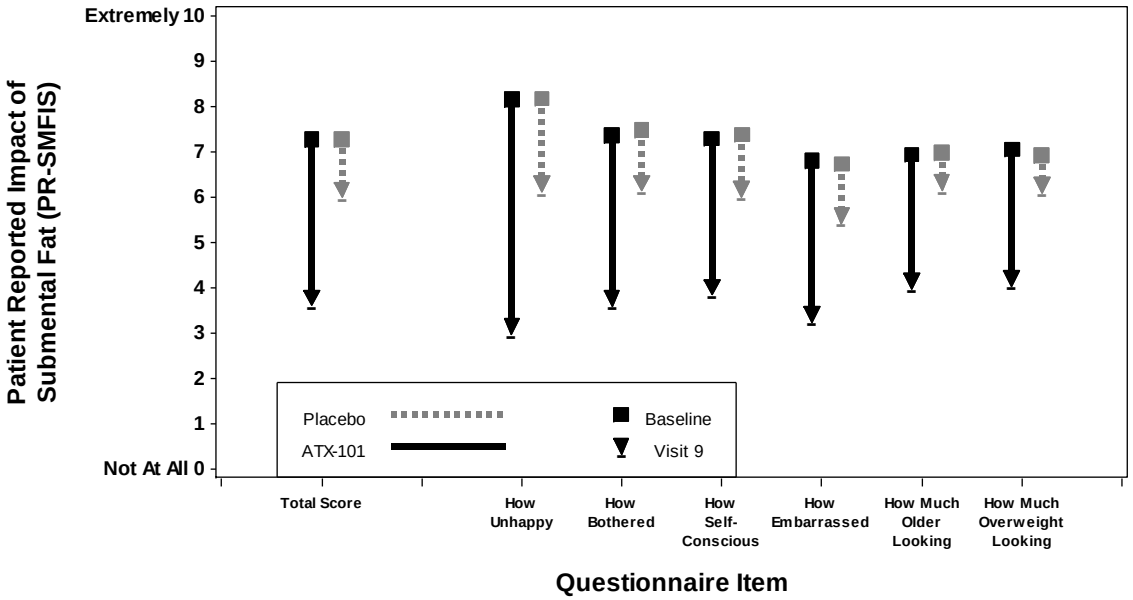


**Figure 5: Mean SMF Impact Change 12 Weeks after Last Treatment**




* p<0.001 for total and all individual items, ATX-101 vs. Placebo.

The supportive EU Phase 3 studies met their prospective primary endpoints and also demonstrated efficacy consistent with the pivotal Phase 3 studies. In long-term follow-up in a subset of subjects who had completed earlier BELKYRA® trials, reductions in SMF were sustained for at least 4 years.

## 5.2 Pharmacokinetic properties

Endogenous deoxycholic acid plasma levels are highly variable within and between individuals; most of this natural bile component is sequestered in the enterohepatic circulation loop. Pharmacokinetics of exogenous deoxycholic acid administered via treatment with BELKYRA® injection was compared against this endogenous background.

### Absorption

Deoxycholic acid from BELKYRA® injection is rapidly absorbed following subcutaneous injection. After dosing with the maximum recommended single treatment with BELKYRA® injection (100 mg), maximum plasma concentrations (mean $C_{max}$) were observed within 30 minutes (median $T_{max}$) after injection and mean $C_{max}$ values were 2- to 3-fold higher than average $C_{max}$ values observed during a 24-hour baseline endogenous period in the absence of BELKYRA® injection. After maximum recommended single treatment dose (100 mg), average deoxycholic acid exposure ($AUC_{0-24}$) was less than 2-fold higher over endogenous exposure. Plasma $AUC_{0-24}$ increased in a dose-proportional manner up to 100 mg. Post-treatment deoxycholic acid plasma levels returned to the endogenous range within 24 hours. No accumulation is expected with the proposed treatment frequency.

### Distribution

The volume of distribution of deoxycholic acid was estimated to be 193 L and is independent of the dose up to 100 mg. Deoxycholic acid is extensively bound to proteins in plasma (98%).

### Metabolism and Excretion

Endogenous deoxycholic acid is a product of cholesterol metabolism and is excreted intact in faeces. Deoxycholic acid from BELKYRA® injection joins the endogenous bile acid pool and

is excreted along with the endogenous deoxycholic acid. Deoxycholic acid is eliminated via hepatic transport proteins from the blood to the bile without any significant contribution of metabolism.

Deoxycholic acid is not an *in vitro* inhibitor of the enzymes CYP1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6 and 3A4. Deoxycholic acid did not induce CYP1A, 2B6 and 3A at a clinical level.

Deoxycholic acid is not an *in vitro* inhibitor of the transporters BSEP, MRP2, MRP4, MDR1, BCRP, OATP1B1, OATP1B3, OAT1, OAT3, OCT1, OCT2, OATP2B1 and ASBT. Deoxycholic acid inhibited NTCP with an IC50 of 2.14 μM *in vitro*.

**Special Populations and Conditions**

**Hepatic Impairment:**

BELKYRA® injection has not been studied in patients with hepatic impairment. Considering the intermittent dose frequency, the small dose administered that represents approximately 3% of the total bile acid pool and the highly variable endogenous deoxycholic acid levels, the pharmacokinetics of deoxycholic acid following BELKYRA® injection is unlikely to be influenced by hepatic impairment.

**Renal Impairment:**

BELKYRA® injection has not been studied in patients with renal impairment. Bile acids including endogenous deoxycholic acid are excreted in the urine in negligible amounts; renal impairment is unlikely to influence deoxycholic acid pharmacokinetics.

## 5.3 Preclinical safety data

**Genotoxicity**

Deoxycholic acid was not genotoxic in a comprehensive battery of tests performed *in vitro* (microbial reverse mutation assay and chromosomal aberration test) and in *in vivo* (micronucleus test) genotoxicity assays.

**Carcinogenicity**

The carcinogenic potential of deoxycholic acid by the subcutaneous route has not been examined in long-term animal studies.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Dibasic sodium phosphate heptahydrate; sodium hydroxide; sodium chloride; hydrochloric acid and water for injections.

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

30 months.

## 6.4 Special precautions for storage

Store below 30°C.

## 6.5 Nature and contents of container

BELKYRA® deoxycholic acid 10 mg/mL solution for injection is supplied in single-use clear, colourless glass vials with a chlorobutyl rubber stopper coated with FluroTec® (ETFE) on the plug surface and an aluminium seal with a polypropylene flip-top lid.

**Pack size:**
One carton with four vials
Each vial contains 2 mL solution for injection.

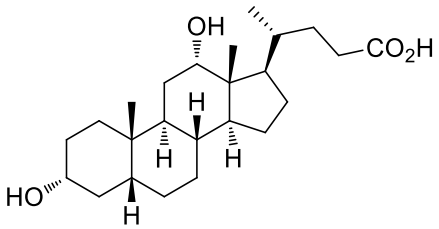
## 6.6 Special precautions for disposal

BELKYRA® injection is for single use in one patient. Any unused medicine or waste material should be disposed of in accordance with local requirements.

## 6.7 Physicochemical properties

BELKYRA® injection contains deoxycholic acid as the active ingredient.

**Chemical structure:**




**Chemical name:** 3α,12α-dihydroxy-5β-cholan-24-oic acid

**Molecular formula:** $C_{24}H_{40}O_4$

**Molecular mass:** 392.57 g/mol

**CAS number:** 83-44-3

# 7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 – Prescription Only Medicine.

AUST R 233201

# 8 SPONSOR

AbbVie Pty Ltd
241 O'Riordan Street
Mascot NSW 2020
Australia

Toll free telephone: 1 800 252 224 (AU)

www.allerganaesthetics.com.au

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Toll free telephone: 0800 659 912 (NZ)

## 9 DATE OF FIRST APPROVAL

21 July 2016

## 10 DATE OF REVISION

14 August 2023

## SUMMARY TABLE OF CHANGES

| Section Changed | Summary of new information |
|---|---|
| **8** | Sponsor details updated |