HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use KYBELLA safely and effectively. See full prescribing information for KYBELLA.

KYBELLA® (deoxycholic acid) injection, for subcutaneous use
Initial U.S. Approval: 2015

----------RECENT MAJOR CHANGES----------

Warnings and Precautions (5.3, 5.5) 09/2026

----------INDICATIONS AND USAGE----------

KYBELLA is a cytolytic drug indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults. (1)

Limitations of Use

KYBELLA is not approved for the treatment of subcutaneous fat outside the submental region, and such use is not recommended. (1, 5.5)

----------DOSAGE AND ADMINISTRATION----------

- Inject KYBELLA into subcutaneous fat tissue in the submental area using an area-adjusted dose of 2 mg/cm^2 (a single treatment of up to 100 mg (up to a total of 10 mL)) that consists of up to a maximum of 50 subcutaneous injections, (2 mg (0.2 mL)) each, spaced 1 cm apart (2.1)
- Up to 6 single treatments may be administered at intervals no less than 1-month apart. (2.1)
- Consider use of ice/cold packs, topical and/or injectable local anesthesia (e.g., lidocaine) to enhance patient comfort (2.3)
- Outline the planned KYBELLA treatment area with a surgical pen and apply a 1 cm injection grid to mark the injection sites (2.3)
- See Full Prescribing Information for additional administration instructions (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

Injection: 10 mg/mL. (3)

----------CONTRAINDICATIONS----------

KYBELLA is contraindicated in patients with an infection at the injection area. (4)

----------WARNINGS AND PRECAUTIONS----------

- *Marginal Mandibular Nerve Injury:* Follow injection technique and do not inject KYBELLA into or in close proximity to the marginal mandibular branch of the facial nerve to avoid this injury. (2.3, 5.1)
- *Dysphagia:* May occur with KYBELLA use. Avoid use in patients with pre-existing dysphagia because use may exacerbate the condition. (5.2)
- *Injection Site Reactions (5.3):*
  - *Hematoma/Bruising:* Use KYBELLA with caution in patients with bleeding abnormalities (e.g., taking antiplatelet or anticoagulant therapy).
  - *Alopecia:* Consider withholding subsequent KYBELLA treatments until resolution.
  - *Ulceration, Necrosis, Nodule, Mass, and Infection:* Discontinue KYBELLA if patients develop injection site ulceration, necrosis, nodule, mass, or infection after KYBELLA administration.
- *Risk of Injecting in Proximity to Vulnerable Anatomic Structures:* Avoid injecting in proximity to vulnerable anatomic structures due to the increased risk of tissue damage and vascular injury. (2.3, 5.4)
- *Serious Adverse Reactions Associated with Unapproved Use Outside the Submental Region:* Serious adverse reactions have been reported following unapproved administration of KYBELLA outside the submental region. KYBELLA is not approved for the treatment of subcutaneous fat outside the submental region. (5.5)

----------ADVERSE REACTIONS----------

The most common adverse reactions (>20% of subjects) include injection site edema/swelling, hematoma, pain, numbness, erythema and induration. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact AbbVie Inc. at 1-800-633-9110 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 09/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

KYBELLA® is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

Limitations of Use

KYBELLA is not approved for the treatment of subcutaneous fat outside the submental region, and such use is not recommended *[see Warnings and Precautions (5.5)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Before injection, see General Considerations for Administration *[*see *Dosage and Administration (2.2, 2.3)]*.

Inject KYBELLA into subcutaneous fat tissue in the submental area using an area-adjusted dose of 2 mg/cm^2 (a single treatment of up to 100 mg (up to a total of 10 mL)) that consists of up to a maximum of 50 subcutaneous injections, (2 mg (0.2 mL)) each, spaced 1 cm apart.

Up to 6 treatments may be administered at intervals no less than 1 month apart.

2.2 Recommendations Prior to KYBELLA Treatment

KYBELLA should be administered by a healthcare provider.

Prior to KYBELLA treatment:

- Screen patients for other potential causes of submental convexity/fullness (e.g., thyromegaly and cervical lymphadenopathy).
- Consider the risks of KYBELLA use 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.
- Visually inspect KYBELLA vials for particulate matter and/or discoloration, and discard the vial if the solution is discolored and/or contains particulate matter (KYBELLA is clear, colorless and free of particulate matter).

Given that patients who have had prior surgical or aesthetic treatment of the submental area may have changes in anatomy/landmarks or scar tissue that may impact the ability of the health care provider to safely administer KYBELLA or to obtain the desired aesthetic result, use KYBELLA with caution in such patients.

2.3 Recommended Preparation and Administration Instructions

The safe and effective use of KYBELLA depends on the use of the correct number and locations of subcutaneous injections, proper needle placement, and administration technique. Prior to administration, 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 *[see Warnings and Precautions (5.1)]*.

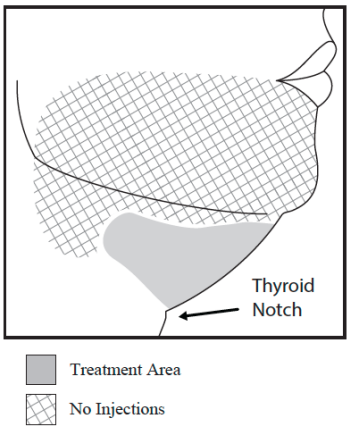
Avoid Injections Near the Area of the Marginal Mandibular Nerve

To avoid injury to the marginal mandibular nerve:

- Inject KYBELLA only within the target submental fat treatment area (see Figures 1 and 3).

- 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).

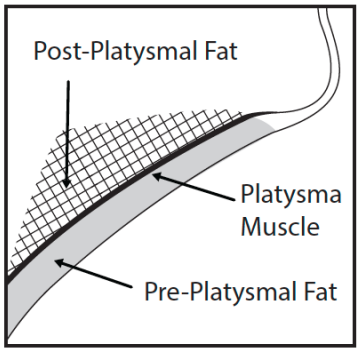
Figure 1. Avoid the Marginal Mandibular Nerve Area



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). 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

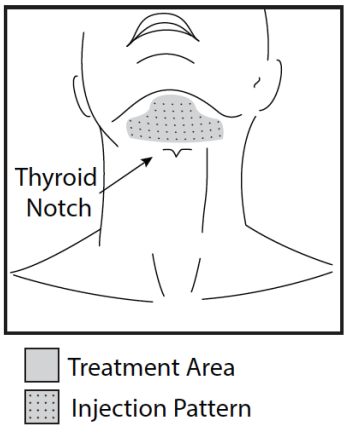


Administration Instructions

Consider use of ice/cold packs, topical and/or injectable local anesthesia (e.g., lidocaine) to enhance patient comfort.

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

Figure 3. Treatment Area and Injection Pattern



Do not inject KYBELLA outside the defined parameters *[see Warnings and Precautions (5.1, 5.3, 5.4)]* and follow these subcutaneous administration instructions:

- Using a large bore needle, draw 1 mL of KYBELLA 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 KYBELLA into the pre-platysmal fat (see Figure 2) next to each of the marked injection sites by advancing the needle perpendicular to the skin.
- Do not withdraw the needle from the subcutaneous fat during injection; this could increase the risk of intradermal exposure and very superficial injections (into the dermis) may result in skin ulceration and necrosis *[see Warnings and Precautions (5.3)]*.
- Avoid injecting into the post-platysmal fat by injecting KYBELLA into fat tissue at the depth of approximately mid-way into the subcutaneous fat layer (Figure 2).
- If at any time resistance is met as the needle is inserted, indicating the possibility of contact with fascial or nonfat tissue, withdraw the needle to an appropriate depth before the injection is administered.
- Avoid injecting into other tissues such as the muscle, salivary glands, lymph nodes; and artery or vein *[see Warnings and Precautions (5.4)]*.
- Upon needle withdrawal, may apply pressure to each injection site as necessary to minimize bleeding; an adhesive dressing may be applied.

After use, discard any remaining solution in the vial. Do not dilute or mix KYBELLA with other compounds.

3 DOSAGE FORMS AND STRENGTHS

Injection: 10 mg/mL, clear, colorless, sterile solution supplied in 2 mL vials intended for single patient use.

4 CONTRAINDICATIONS

KYBELLA is contraindicated in patients with an infection in the injection area.

5 WARNINGS AND PRECAUTIONS

5.1 Marginal Mandibular Nerve Injury

Cases of marginal mandibular nerve injury, manifested as an asymmetric smile or facial muscle weakness (paresis), were reported in KYBELLA-treated patients during clinical trials. All

marginal mandibular nerve injuries reported from the trials resolved without additional treatment (range 1-298 days, median 44 days).

To avoid the potential for marginal mandibular nerve injury, do not inject KYBELLA into or in close proximity to the marginal mandibular branch of the facial nerve *[see Dosage and Administration (2.3)]*.

5.2 Dysphagia

Difficulty swallowing (dysphagia) occurred in KYBELLA-treated patients in clinical trials in the setting of administration site reactions, e.g., pain, swelling, and induration of the submental area. Cases of dysphagia resolved without additional treatment (range 1-81 days, median 3 days). Subjects with current or prior history of dysphagia were excluded from clinical trials.

Avoid use of KYBELLA in patients with a current or prior history of dysphagia because KYBELLA use may exacerbate the condition.

5.3 Injection Site Reactions

Injection Site Hematoma or Bruising

In clinical trials, 72% of subjects treated with KYBELLA had an injection site hematoma or bruising *[see Adverse Reactions (6.1)]*.

Use KYBELLA with caution in patients with bleeding abnormalities (e.g., taking antiplatelet or anticoagulant therapy) as excessive bleeding or bruising in the treatment area may occur.

Injection Site Alopecia

Cases of injection site alopecia have been reported with KYBELLA administration. The onset and duration of this adverse reaction may vary among individuals and may persist.

Consider withholding subsequent KYBELLA treatments until resolution of this adverse reaction.

Injection Site Ulceration, Necrosis, Nodule, Mass, and Infection

Very superficial injections (into the dermis) of KYBELLA may result in skin ulceration and necrosis *[see Dosage and Administration (2.3)]*. Cases of injection site ulceration, necrosis, nodule (≤ 3 cm in diameter), mass (> 3 cm in diameter), and infection have been reported with KYBELLA administration. Nodules or masses may occur following initial or subsequent KYBELLA administration. Some nodules and masses may not resolve and medical intervention may be required. Some cases of injection site infection have included cellulitis and abscess requiring intravenous antibiotic treatment and incision and drainage.

Discontinue KYBELLA if patients develop injection site ulceration, necrosis, nodule, mass, or infection after KYBELLA administration.

5.4 Risk of Injecting in Proximity to Vulnerable Anatomic Structures

To avoid potential tissue damage, do not inject KYBELLA into or in close proximity (1-1.5 cm) to salivary glands, lymph nodes and muscles.

Avoid inadvertent injection directly into an artery or a vein as it can result in vascular injury.

5.5 Serious Adverse Reactions Associated with Unapproved Use Outside the Submental Region

Serious adverse reactions have been reported following unapproved administration of KYBELLA outside the submental region (e.g., blurred or reduced vision with periorbital use,

muscle or nerve injury including facial paresis and paresthesia). Cases of injection site nodules (≤ 3 cm in diameter) and masses (> 3 cm in diameter) have also been reported following initial or subsequent administration of KYBELLA outside the submental region. The nodules and masses may not resolve and medical intervention may be required.

KYBELLA is not approved for the treatment of subcutaneous fat outside the submental region *[see Indications and Usage (1)]*.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In two double-blind, placebo-controlled clinical trials 513 subjects were treated with KYBELLA and 506 subjects were treated with placebo *[see Clinical Studies (14)]*. Subjects received up to 6 treatments at least 1 month apart and were followed for up to 6 months after the last received treatment.

The most commonly reported adverse reactions are listed below (Table 1).

Table 1. Adverse Reactions in the Pooled Trials 1 and 2[a]

Adverse reactions	**KYBELLA (N=513) n (%)**	**Placebo (N=506) n (%)**
Injection site reactions	492 (96%)	411 (81%)
edema/swelling	448 (87%)	218 (43%)
hematoma/bruising	368 (72%)	353 (70%)
pain	356 (70%)	160 (32%)
numbness	341 (66%)	29 (6%)
erythema	136 (27%)	91 (18%)
induration	120 (23%)	13 (3%)
paresthesia	70 (14%)	20 (4%)
nodule	68 (13%)	14 (3%)
pruritus	64 (12%)	30 (6%)
skin tightness	24 (5%)	6 (1%)
site warmth	22 (4%)	8 (2%)
nerve injury[b]	20 (4 %)	1 (<1%)
Headache	41 (8%)	20 (4%)
Oropharyngeal pain	15 (3%)	7 (1%)
Hypertension	13 (3%)	7 (1%)
Nausea	12 (2%)	3 (1%)
Dysphagia	10 (2%)	1 (<1%)

[a] Adverse reactions that occurred in ≥ 2% KYBELLA treated subjects and at greater incidence than placebo

[b] Marginal mandibular nerve paresis

Other adverse reactions associated with the use of KYBELLA included injection site hemorrhage, injection site discoloration, pre-syncope/syncope, lymphadenopathy, injection site urticaria, and neck pain.

Adverse reactions that lasted more than 30 days and occurred in more than 10% of KYBELLA-treated subjects were injection site numbness (42%), injection site edema/swelling (20%), injection site pain (16%), and injection site induration (13%).

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of KYBELLA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to KYBELLA exposure.

- *Administration Site Conditions*: injection site ulceration, necrosis, mass, infection, alopecia, and scarring.
- *Immune System Disorders:* Hypersensitivity reactions including rash, urticaria, and itching.
- *Nervous System Disorders:* Oral hypoaesthesia and oral paraesthesia.
- *Procedural Complications:* Vascular injury due to inadvertent intravascular injection.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled trials of KYBELLA in pregnant women to inform the drug-associated risk. In animal reproduction studies, no fetal harm was observed with the subcutaneous administration of deoxycholic acid to rats during organogenesis at doses up to 5 times the maximum recommended human dose (MRHD) of 100 mg *[see Data]*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk of major birth defects in the U.S. general population is 2-4% and of miscarriage is 15-20% of clinically recognized pregnancies.

Data

Animal Data: Embryofetal development studies have been performed in rats and rabbits using subcutaneous doses of deoxycholic acid administered during the period of organogenesis. For the basis of comparing animal to human doses, the MRHD is 1.7 mg/kg (100 mg/60 kg). No evidence of fetal harm was observed in rats at up to the highest dose tested (50 mg/kg) which is 5-fold higher than the MRHD of KYBELLA based on a mg/m^2 comparison. However, missing intermediate lung lobe was noted in rabbits at all dose levels tested including the lowest dose (10 mg/kg) which is 2-fold higher than the MRHD of KYBELLA based on a mg/m^2 comparison. These effects may be related to maternal toxicity, which was also seen at all dose levels tested.

8.2 Lactation

Risk Summary

There is no information available on the presence of synthetic deoxycholic acid in human milk, the effects of the drug on the breastfed infant or the effects of the drug on milk production.

The developmental and health benefits of breastfeeding should be considered along with the

mother's clinical need for KYBELLA and any potential adverse effects on the breastfed child from KYBELLA or from the underlying maternal condition.

8.4 Pediatric Use

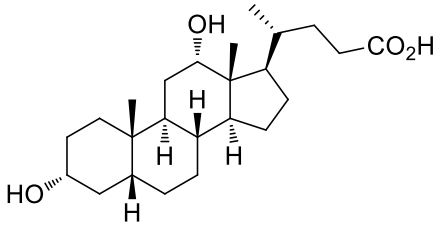
Safety and effectiveness of KYBELLA have not been established in pediatric patients and KYBELLA is not recommended for use in children or adolescents.

8.5 Geriatric Use

The clinical trials of KYBELLA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger adult subjects.

11 DESCRIPTION

The chemical name of deoxycholic acid is 3α,12α-dihydroxy-5β-cholan-24-oic acid, and its molecular formula is $C_{24}H_{40}O_4$, and its molecular weight is 392.57 g/mol. The chemical structure of deoxycholic acid is:



KYBELLA (deoxycholic acid) injection, 10 mg/mL is a clear colorless, sterile solution for subcutaneous use. Each 2 mL vial of KYBELLA contains 20 mg of deoxycholic acid, a cytolytic agent, as the active ingredient and the following inactive ingredients: benzyl alcohol (18 mg), dibasic sodium phosphate (2.84 mg), sodium chloride (8.76 mg), sodium hydroxide (2.86 mg) in water for injection, USP. Hydrochloric acid and additional sodium hydroxide are added as necessary to adjust the formulation to pH 8.3. Each vial is for single patient use.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

KYBELLA is a cytolytic drug, which when injected into submental fat - in patients with moderate to severe convexity or fullness associated with submental fat - physically destroys the cell membrane causing lysis.

12.2 Pharmacodynamics

Cardiac Electrophysiology

At the recommended deoxycholic acid dose, clinically significant QTc interval prolongation was not observed.

12.3 Pharmacokinetics

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.

Absorption and Distribution

After KYBELLA subcutaneous injection, deoxycholic acid was rapidly absorbed. After dosing with the recommended single treatment KYBELLA dose (100 mg)

- Maximum plasma concentrations of deoxycholic acid (mean C_{max}) were observed with a median T_{max} of 18 minutes after injection.
- Mean (±SD) deoxycholic acid exposure (AUC_{0-24}) was 7896 ± 2269 ng.hr/mL and was 1.6-fold higher over endogenous exposure.

The mean (±SD) C_{max} value was 1024 ± 304 ng/mL and was 3.2-fold higher than average C_{max} values observed during a 24-hour baseline endogenous period in the absence of KYBELLA. Post-treatment deoxycholic acid plasma levels returned to the endogenous range within 24 hours. No accumulation is expected with the proposed treatment frequency.

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 feces. Deoxycholic acid is not metabolized to any significant extent under normal conditions. Deoxycholic acid from KYBELLA joins the endogenous bile acid pool in the enterohepatic circulation and is excreted along with the endogenous deoxycholic acid.

Drug Interaction Studies

In Vitro Assessment of Drug Interactions: Results from in vitro studies indicate that deoxycholic acid does not inhibit or induce human cytochrome P450 (CYP) enzymes at clinically relevant concentrations. Deoxycholic acid does not inhibit the following transporters: P-gp, BCRP, MRP4, MRP2, OATP1B1, OATP2B1, OATP1B3, OCT1, OCT2, OAT1, OAT3, NTCP, and ASBT.

Specific Populations

Patients with Hepatic Impairment: KYBELLA has not been studied in subjects 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 KYBELLA injection is unlikely to be influenced by hepatic impairment.

Male and Female Patients: Deoxycholic acid pharmacokinetics were not influenced by sex.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of deoxycholic acid.

Deoxycholic acid was negative in a battery of in vitro (Ames test and chromosomal aberration assay in human lymphocytes) and in vivo (rat erythrocyte micronucleus assay) genetic toxicology assays.

No effects on fertility were observed in male and female rats administered deoxycholic acid at subcutaneous doses up to 50 mg/kg (5 times the MRHD based on a mg/m^2 comparison) once weekly prior to and during the mating period and through gestation day 7 in female rats.

14 CLINICAL STUDIES

Two randomized, multi-center, double-blind, placebo-controlled trials (Trials 1 and 2) of identical design were conducted to evaluate KYBELLA for use to improve the appearance of moderate to severe convexity or fullness associated with submental fat. The trials enrolled healthy

adults (ages 19 to 65, BMI ≤ 40 kg/m^2) with moderate or severe convexity or fullness associated with submental fat (i.e., grade 2 or 3 on 5-point grading scales, where 0 = none and 4 = extreme), as judged by both clinician and subject ratings. Subjects received up to 6 treatments with KYBELLA (N=514, combined trials) or placebo (N=508, combined trials) at no less than 1 month intervals. Use of ice/cold packs, topical and/or injectable local anesthesia was allowed during the clinical trials. Injection volume was 0.2 mL (2 mg) per injection site, spaced 1 cm apart into the submental fat tissue, which is also expressed in dose per area as 2 mg/cm^2. For each treatment session a maximum of 100 mg (10 mL) was permitted over the entire treatment area. Subjects were administered an average of 64 mg (6.4 mL) at the first treatment session, and subjects who received all six treatments were administered an average of 44 mg (4.4 mL) at the sixth treatment session. In these trials, 59% of subjects received all six treatments.

Baseline Demographics and Important Disease Characteristics

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 White (87%) and African American (8%). At baseline, 51% of the subjects had a clinician-rated submental fat severity rating of moderate submental fat rating (graded as 2 on a 0 to 4 scale) and 49% had a severe submental fat rating (graded as 3 on a 0 to 4 scale) and without excessive skin laxity.

Key Endpoints

The co-primary efficacy assessments in these trials were based on at least 2-grade and at least 1-grade improvements in submental convexity or fullness on the composite of clinician-reported and patient-reported ratings of submental fat 12 weeks after final treatment. Additionally, changes in submental fat volume were evaluated in a subset of subjects (N=449, combined trials) using magnetic resonance imaging (MRI). Visual and emotional impacts of submental fat (happy, bothered, self-conscious, embarrassed, looking older or overweight) were also evaluated using a 6-question survey, with each question rated from 0 (not at all) to 10 (extremely/very much).

Efficacy Results

In Trials 1 and 2, reductions in submental fat volume were observed more frequently in the KYBELLA group compared to the placebo group as measured by the composite clinician and patient ratings (Table 2). The composite response rates by visit are presented in Figure 4.

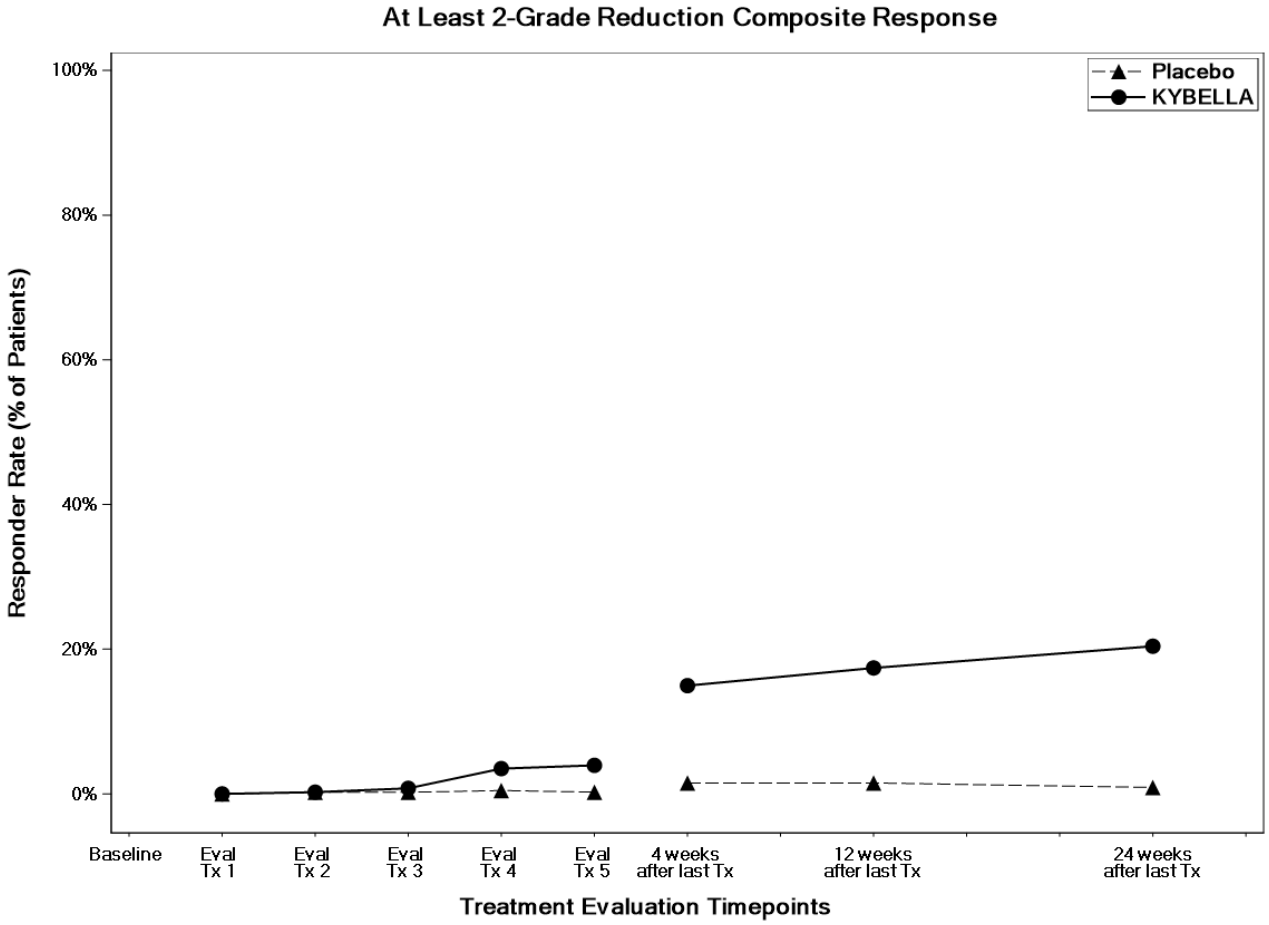
Table 2. ≥ 2-Grade and ≥ 1-Grade Composite Clinician Response and Composite Patient Response 12 Weeks After Final Treatment in Adult Patients with Moderate to Severe Convexity or Fullness Associated with Submental Fat

	Trial 1		**Trial 2**	
Endpoint	**KYBELLA** (N=256)	**Placebo** (N=250)	**KYBELLA** (N=258)	**Placebo** (N=258)
2-Grade Composite Response [a]	13.4%	<0.1%	18.6%	3.0%
1-Grade Composite Response [b]	70.0%	18.6%	66.5%	22.2%

[a] At least 2 grade reduction on both the clinician-reported and patient-reported ratings of submental fat

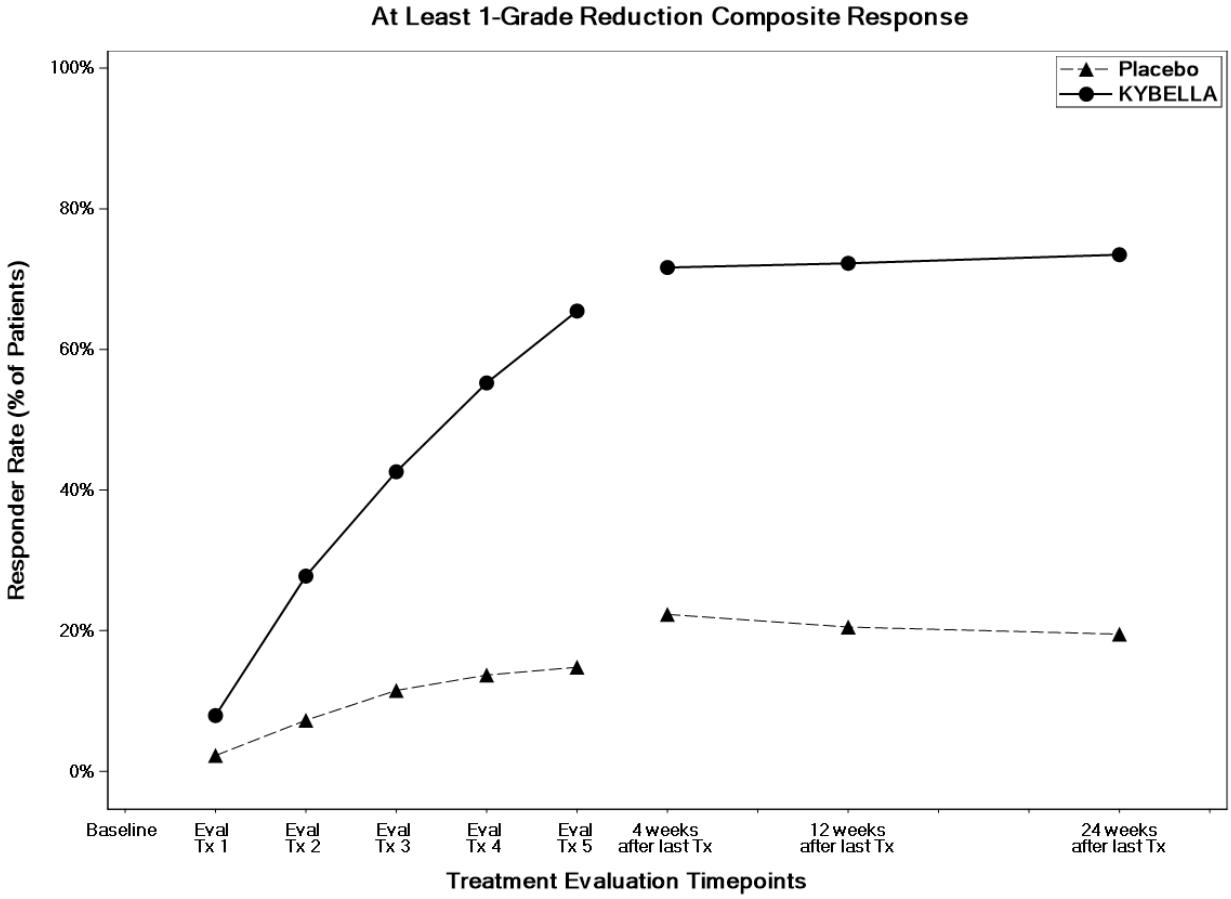
[b] At least 1 grade reduction on both the clinician-reported and patient-reported ratings of submental fat

Figure 4. Subjects with ≥ 2-Grade on Both the Clinician-Reporting Ratings and the Patient Response in Adult Patients with Moderate to Severe Convexity or Fullness Associated with Submental Fat



Subjects were followed up 4, 12 and 24 weeks after the last¬ treatment. Forty-one percent of subjects received fewer than 6 treatments and entered the post-treatment period earlier than Week 24.

Figure 5. Subjects with ≥ 1-Grade on Both the Composite Clinician Response and the Composite Patient Response in Adult Patients with Moderate to Severe Convexity or Fullness Associated with Submental Fat



Subjects were followed up 4, 12 and 24 weeks after the last treatment. Forty-one percent of subjects received fewer than 6 treatments and entered the post-treatment period earlier than Week 24.

A greater proportion of KYBELLA-treated subjects had at least a 10% reduction in submental fat volume (evaluated by MRI) as compared to placebo-treated subjects (43% vs 5%, respectively).

The overall patient-reported satisfaction and self-perceived visual attributes showed greater improvement in the KYBELLA group than in the placebo group.

16 HOW SUPPLIED/STORAGE AND HANDLING

KYBELLA (deoxycholic acid) injection, 10 mg/mL is a clear, colorless, sterile solution supplied in 2 mL, single patient use vials in the following dispensing pack:

- vials, NDC 61168-101-04

Store at 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

KYBELLA has a unique hologram on the vial label. If you do not see a hologram, do not use the product and call 1-800-633-9110.

Each vial is for a single patient use.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Advise patients to contact their healthcare providers if they develop signs of marginal mandibular nerve paresis (e.g., asymmetric smile, facial muscle weakness) or difficulty swallowing, or if existing symptoms worsen *[see Warnings and Precautions (5.1, 5.2)]*.

Advise patients to contact their healthcare providers if they develop injection site hematoma, brusing, alopecia, ulceration, necrosis, nodule, mass, infection, pain, numbness, induration, or paresthesia from the treatment area *[see Warnings and Precautions (5.3)]*.

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Manufactured for:
AbbVie Inc.
North Chicago, IL 60064

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Allergan Aesthetics
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PATIENT INFORMATION
KYBELLA® (kye be lah)
(deoxycholic acid) injection
for subcutaneous use

What is KYBELLA?

KYBELLA is a prescription medicine used in adults to improve the appearance and profile of moderate to severe fat below the chin (submental fat), also called "double chin."

The use of KYBELLA for the treatment of fat outside of the submental area is not recommended.

It is not known if KYBELLA is safe and effective in children under 18 years of age.

Do not receive KYBELLA if you have an infection in the treatment area.

Before receiving KYBELLA, tell your healthcare provider about all of your medical conditions, including if you:

- have had or plan to have surgery on your face, neck, or chin
- have had cosmetic treatments on your face, neck, or chin
- have had or have medical conditions in or near the neck area
- have had or have trouble swallowing
- have bleeding problems
- are pregnant or plan to become pregnant. It is not known if KYBELLA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if KYBELLA passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take a medicine that prevents the clotting of your blood (antiplatelet or anticoagulant medicine).

How will I receive KYBELLA?

- KYBELLA is injected into the fat under your chin (up to 50 injections under your skin) by your healthcare provider.
- KYBELLA injections may be given at least 1 month apart. You and your healthcare provider will decide how many treatments you need.

What are the possible side effects of KYBELLA?

KYBELLA can cause serious side effects, including:

- **Nerve injury in the jaw that can cause an uneven smile or facial muscle weakness.**
- **Trouble swallowing.**
- **Injection site problems including:**
  - a collection of blood under the skin (hematoma) or bruising
  - damage to an artery or vein if KYBELLA is inadvertently injected into it
  - hair loss
  - open sores (ulcers)
  - damage and tissue cell-death (necrosis) around the injection site
  - nodules (≤ 3 cm in diameter) or mass (> 3 cm in diameter). Some nodules and masses may not resolve, and medical treatment, may be required.
  - Infection
- **KYBELLA can cause serious side effects when injected into areas of the body other than below the chin (submental area) including:**
  - blurred or reduced vision when injected around the eyes
  - muscle or nerve damage, including numbness and tingling in the face
  - lumps or nodules where the injection was given. These lumps or nodules may not resolve in time and medical treatment, may be required

  Call your healthcare provider if you:
  - begin to develop weakness in the muscles of your face, or your smile becomes uneven
  - you have difficulty swallowing, or if any of the symptoms that you already have get worse
  - develop redness, pain, open sores, or drainage at or from the treatment area.

The most common side effects of KYBELLA include:

- swelling
- pain
- numbness
- redness
- areas of hardness in the treatment area

These are not all of the possible side effects of KYBELLA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of KYBELLA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for more information about KYBELLA that is written for health professionals.

What are the ingredients in KYBELLA?

Active ingredient: deoxycholic acid

Inactive ingredients: benzyl alcohol, dibasic sodium phosphate, hydrochloric acid, sodium chloride, sodium hydroxide and water for injection, USP.

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This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 09/2026

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