## RECONSTITUTION GUIDANCE



## RECONSTITUTION FOR FDA-APPROVED GLABELLAR LINES DOSE

# FOR EVERY 100-UNIT DAXXIFY® VIAL, RECONSTITUTE WITH 1.2 ML OF STERILE SALINE\*



Inject 0.1 mL into 5 glabellar lines injection points 40U (0.18 ng) in 0.5 mL per glabellar lines treatment



0.1 mL contains 8 units once reconstituted

#### PREPARATION

#### 1. USE 1.2 ML OF DILUENT

To reconstitute DAXXIFY<sup>®</sup>, draw up 1.2 mL of sterile saline.<sup>1\*</sup>

#### 2. INJECT DILUENT SLOWLY

Clean the exposed rubber stopper on the DAXXIFY® vial with an alcohol swab. Slowly inject the saline diluent into the DAXXIFY® vial.<sup>1</sup>

### 3. MIX THE SOLUTION

Swirl gently to ensure mixing. Record the date of the reconstitution on vial/syringe sticker.<sup>1</sup>

### 4. INSPECT THE SOLUTION

The reconstituted solution should be clear to slightly opalescent, colorless, and free of particulate matter. The reconstituted solution may temporarily appear cloudy. **DO NOT USE** if the solution remains cloudy or discolored or contains flakes or particles.<sup>1</sup>

### **5. READY FOR TREATMENT**

Draw an appropriate dose into a new sterile syringe.





More than 70% of injectors do not reconstitute a conventional neuromodulator following prescribing information guidance. Using a different reconstitution volume can lead to unintended safety consequences. To mitigate this safety risk, use the table below to ensure the FDA-approved 40U dose of DAXXIFY® (daxibotulinumtoxinA-lanm) injection is administered.<sup>2</sup>

#### CONVENTIONAL NEUROMODULATOR

(100-unit vial, 0.18 ng per 20U treatment)

RECONSTITUTION VOLUME	1.0 mL	2.0 mL	2.5 mL	3.0 mL	4.0 mL
GLABELLAR LINES TREATMENT DOSE	20U	20U	200	200	200
TOTAL GLABELLAR LINES TREATMENT VOLUME	0.2 mL	0.4 mL	0.5 mL	0.6 mL	0.8 mL
PUSH VOLUME For each of the 5 injection points (and the corresponding units)	0.04 mL (4 Units)	0.08 mL (4 Units)	0.10 mL (4 Units)	<b>0.12 mL</b> (4 Units)	<b>0.16 mL</b> (4 Units)

### **DAXXIFY**®

(100-unit vial, 0.18 ng per 40U treatment)	ON LABEL						
RECONSTITUTION VOLUME	0.5 mL	1.0 mL	1.2 mL	1.5 mL	2.0 mL		
GLABELLAR LINES TREATMENT DOSE	40U	40U	40U	40U	40U		
TOTAL GLABELLAR LINES TREATMENT VOLUME	0.2 mL	0.4 mL	0.5 mL	0.6 mL	0.8 mL		
PUSH VOLUME For each of the 5 injection points (and the corresponding units)	0.04 mL (8 Units)	0.08 mL (8 Units)	0.10 mL (8 Units)	0.12 mL (8 Units)	0.16 mL (8 Units)		

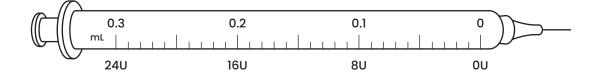
#### INDICATION

DAXXIFY® (daxibotulinumtoxinA-lanm) injection is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

Please see Important Safety Information, including Boxed Warning, on back.

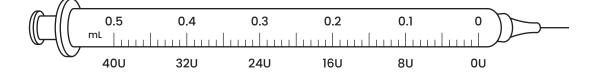
• DRAW UP 0.5 ML IN 2 SYRINGES 0.3 mL in one syringe and 0.2 mL in another syringe

## • EACH TICK MARK REPRESENTS 0.01 ML AND WOULD CONTAIN 0.8U



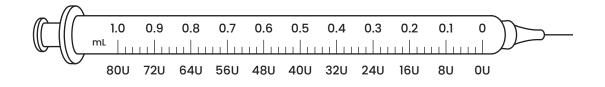
0.5 ML SYRINGE

- DRAW UP 0.5 ML IN A SYRINGE
- EACH TICK MARK REPRESENTS 0.01 ML AND WOULD CONTAIN 0.8U

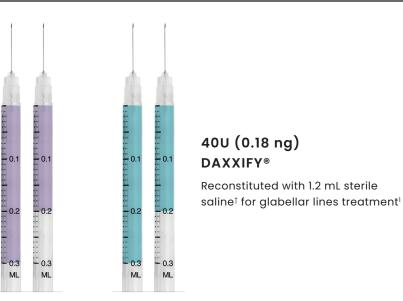


1.0 ML SYRINGE

- DRAW UP 0.5 ML IN A SYRINGE
- EACH TICK MARK REPRESENTS 0.02 ML AND WOULD CONTAIN 1.6U\*



\*Representation is of common 1.0 mL syringe but some syringes may label barrels differently (ie, 0.01 mL tick marks represent 1U). Please check your syringe tick marks carefully.



## 20U (0.18 ng) BOTOX® COSMETIC

Reconstituted with 2.5 mL sterile saline<sup>†</sup> for glabellar lines treatment<sup>3</sup>



Reconstituted with 1.2 mL sterile saline<sup>†</sup> for glabellar lines treatment<sup>1</sup>



0.1

ML

0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1.0

ML

## 20U (0.18 ng) BOTOX® COSMETIC

Reconstituted with 2.5 mL sterile saline<sup>†</sup> for glabellar lines treatment<sup>3</sup>



Reconstituted with 1.2 mL sterile saline<sup>†</sup> for glabellar lines treatment<sup>1</sup>



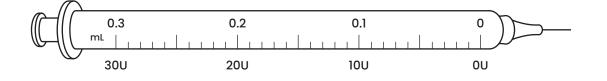


## 20U (0.18 ng) BOTOX® COSMETIC

Reconstituted with 2.5 mL sterile saline<sup>†</sup> for glabellar lines treatment<sup>3</sup>

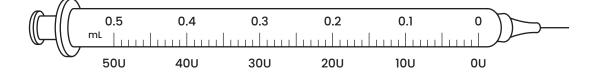
• DRAW UP 0.4 ML IN 2 SYRINGES 0.24 mL in one syringe and 0.16 mL in another syringe

## • EACH TICK MARK REPRESENTS 0.01 ML AND WOULD CONTAIN 1U



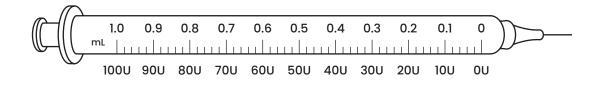
0.5 ML SYRINGE

- DRAW UP 0.4 ML IN A SYRINGE
- EACH TICK MARK REPRESENTS 0.01 ML AND WOULD CONTAIN 1U

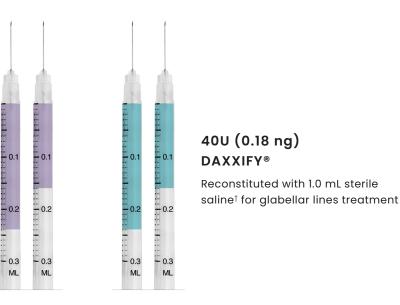


1.0 ML SYRINGE

- DRAW UP 0.4 ML IN A SYRINGE
- EACH TICK MARK REPRESENTS 0.02 ML AND WOULD CONTAIN 2U\*



\*Representation is of common 1.0 mL syringe but some syringes may label barrels differently (ie, 0.01 mL tick marks represent 1U). Please check your syringe tick marks carefully.



## 20U (0.18 ng) BOTOX® COSMETIC

Reconstituted with 2.0 mL sterile saline<sup>†</sup> for glabellar lines treatment



Reconstituted with 1.0 mL sterile saline<sup>†</sup> for glabellar lines treatment



0.1

-0.5 ML

0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1.0

ML

## 20U (0.18 ng) BOTOX® COSMETIC

Reconstituted with 2.0 mL sterile saline<sup>†</sup> for glabellar lines treatment



Reconstituted with 1.0 mL sterile saline<sup>†</sup> for glabellar lines treatment





## 20U (0.18 ng) BOTOX® COSMETIC

Reconstituted with 2.0 mL sterile saline<sup>†</sup> for glabellar lines treatment

#### WARNING: DISTANT SPREAD OF TOXIN EFFECT

The effects of DAXXIFY® (daxibotulinumtoxinA-lanm) and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. DAXXIFY® is not approved for the treatment of spasticity or any conditions other than glabellar lines.

#### IMPORTANT SAFETY INFORMATION

#### Contraindications

DAXXIFY® contraindications include hypersensitivity to any botulinum toxin preparation or any of the components in the formulation and infection at the injection site(s).

#### Warnings and Precautions

Please refer to Boxed Warning for Distant Spread of Toxin Effect.

The potency Units of DAXXIFY® are not interchangeable with other preparations of other botulinum toxin products. Recommended dose and frequency of administration should not be exceeded. Patients should seek immediate medical attention if respiratory, speech or swallowing difficulties occur. Use caution when administering to patients with preexisting cardiovascular disease. Concomitant neuromuscular disorders may exacerbate clinical effects of treatment.

#### **Adverse Reactions**

The most commonly observed adverse reactions (≥1%) were headache (6%), eyelid ptosis (2%) and facial paresis (1%).

#### **Drug Interactions**

Co-administration of DAXXIFY® and aminoglycoside antibiotics, anticholinergic agents or any other agents interfering with neuromuscular transmission or muscle relaxants should only be performed with caution as the effect of DAXXIFY® may be potentiated. The effect of administering different botulinum neurotoxins during course of treatment with DAXXIFY® is unknown.

#### **Use in Specific Populations**

DAXXIFY® is not recommended for use in children or pregnant women.

#### Please see DAXXIFY® full Prescribing Information, including Boxed Warning and Medication Guide.

DAXI-001720.2

#### REFERENCES

1. DAXXIFY® Prescribing Information. Revance Therapeutics, Inc; 2022.

2. Data on File. Reconstitution Survey. Kx Advisors, April 2023.

3. BOTOX® Cosmetic. Prescribing Information. Allergan Inc; 2020.



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