

INSTRUCTIONS FOR USE

SOFDRA™
(sof-drah)
(sofipronium)
topical gel, 12.45%

These Instructions for Use contain information on how to use SOFDRA.

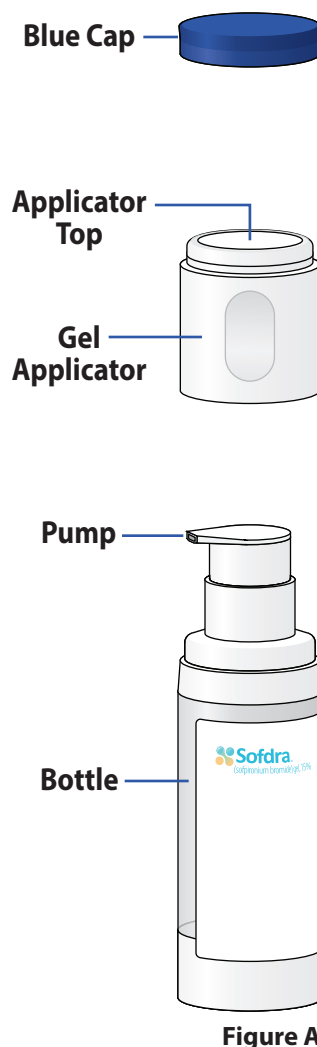
STOP

Read the Instructions for Use before you start using SOFDRA and each time you get a refill.

This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

If you have questions, ask your pharmacist or healthcare provider.

SOFDRA Parts



Important Information You Need to Know Before Applying SOFDRA

- SOFDRA gel should be used before bedtime.
- SOFDRA gel is for the underarms only. Do not apply SOFDRA to any other part of the body. Do not apply SOFDRA to broken skin.
- One complete dose of SOFDRA gel is 1 pump per underarm. Do not use more than 1 pump per underarm, regardless of underarm size.
- Do not use SOFDRA if the expiration date has passed.
- Do not apply SOFDRA if you:
 - Shaved your underarms or applied deodorant to your armpits within the last 8 hours.
 - Exercised, showered, or washed your underarms within the last 30 minutes.
- Avoid touching the gel with your hands or fingers.
- Do not get the gel on or near your eyes.
- Always apply and spread SOFDRA gel using the provided Applicator. Do not spread gel with your hands or with a towel.
- Let SOFDRA gel dry for 5 minutes after it is applied.
 - Do not put on clothing until gel has dried completely.
 - Do not smoke or go near an open flame until the gel is dry. SOFDRA gel is flammable.
- Do not touch your underarms after applying the gel.
- Always wash your hands with soap and water right away after applying SOFDRA gel to avoid spreading any gel residue to any other parts of your body.
- Do not shower or wash your underarms for at least 8 hours after applying SOFDRA.
- The Bottle contains 30 days of medicine. After applying 30 daily doses of SOFDRA gel, throw away the Blue Cap, Applicator, and Bottle into the household trash.

Prepare to Apply SOFDRA

1 Check if you are ready to apply SOFDRA

1.1 Apply SOFDRA before bedtime (Figure B).

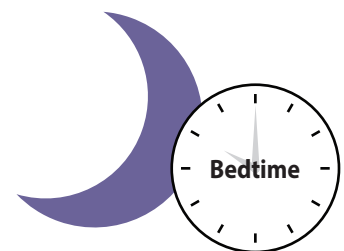


Figure B

1.2 Before applying SOFDRA make sure that you:

- Do Not shave your underarms within the last 8 hours.
- Do Not apply deodorant to your underarms within the last 8 hours.
- Do Not exercise within the last 30 minutes.
- Do Not shower or wash your underarms within the last 30 minutes.

2 Gather supplies

2.1 Gather the following supplies.

- SOFDRA (Figure C)



Figure C

- Clean towel (Figure D)



Figure D

3 Check the expiration date

3.1 Check the expiration date ("EXP") on the Bottle label to make sure it has not passed (Figure E).

Do not use SOFDRA if the expiration date has passed.



Figure E

4 Remove Blue Cap and Applicator from Bottle

4.1 Pull the Blue Cap straight off the Bottle and set it aside (Figure F).

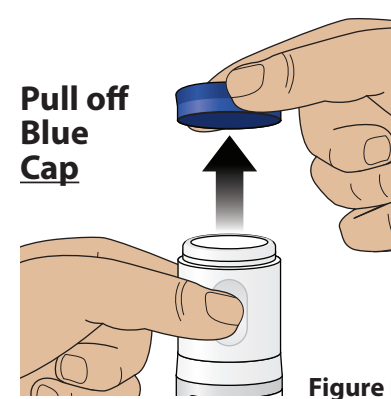


Figure F

4.2 Pull the gel Applicator straight off the Bottle and set it aside (Figure G).

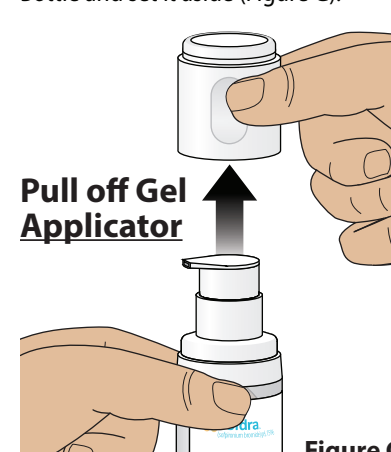


Figure G

Are you using a new SOFDRA Bottle? **No**

Yes If Yes, go to step 5.
If No, skip step 5 and go to step 6.

5 Prime the pump (First time use only)

Important: Priming the pump is required the first time you use a new Bottle. The purpose of priming is to make sure the pump works correctly and dispenses gel properly.

5.1 Hold the Bottle over a sink. Press the pump all the way down 1 to 2 times, or until you see gel coming out (Figure H).



Figure H

5.2 Use water to wash down any gel in the sink (Figure I).

Do not touch or use any of the gel residue from the sink.



Figure I

6 Prepare underarms

6.1 Remove all clothing around both underarms (Figure J). Note: It is okay to use SOFDRA on underarms with hair or new growth (stubble).

Do not apply SOFDRA to any other part of the body. Do not apply SOFDRA to broken skin.

Expose both underarms

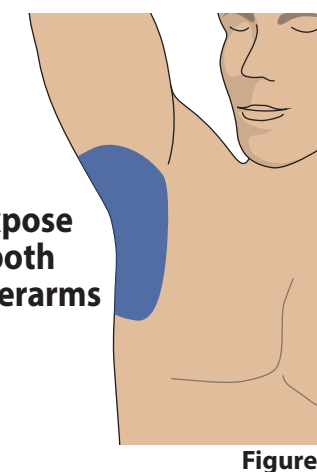


Figure J

6.2 Dry both underarms with a clean towel before applying SOFDRA gel (Figure K).

Dry both underarms



Figure K

Apply 1 Pump of SOFDRA to Each Armpit

7 Apply 1 pump of SOFDRA gel to first underarm

7.1 Hold the Applicator steady and level with the top (flat area) pointing up (Figure L).

Put 1 full pump of gel onto the top of the Applicator (Figure L).

Avoid touching the gel with your hands or fingers.

- Do not apply more than 1 pump per underarm, regardless of size.
- Do not tilt the Applicator until you apply it to your underarm to avoid spilling the gel.
- Do not put the gel inside of the opening at the bottom of the Applicator.



Figure L

7.2 Spread SOFDRA gel around the whole area of the first underarm using the Applicator (Figure M).

Always apply and spread SOFDRA gel using the provided Applicator.

- Do not spread gel with your hands or with a towel.
- Do not touch your underarms after applying the gel.

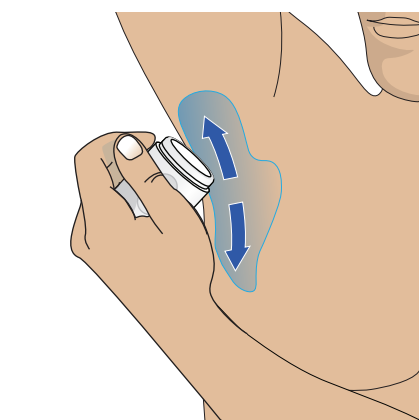


Figure M

8 Apply 1 pump of SOFDRA gel to second underarm

8.1 Hold the Applicator steady and level with the top (flat area) pointing up (Figure N).

Put 1 full pump of gel onto the top of the Applicator (Figure N).

Avoid touching the gel with your hands or fingers.

- Do not apply more than 1 pump per underarm, regardless of size.
- Do not tilt the Applicator until you apply it to your underarm to avoid spilling the gel.
- Do not put the gel inside of the opening at the bottom of the Applicator.



Figure N

8.2 Spread SOFDRA gel around the whole area of the second underarm using the Applicator (Figure O).

Always apply and spread SOFDRA gel using the provided Applicator.

- Do not spread gel with your hands or with a towel.
- Do not touch your underarms after applying the gel.

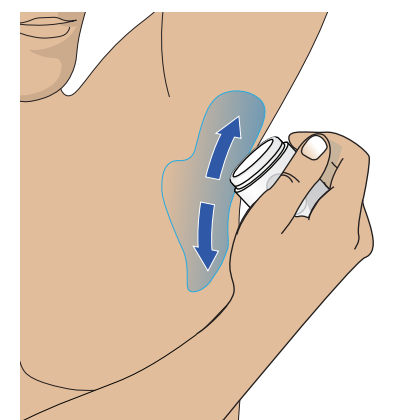


Figure O

9 Let SOFDRA gel dry

9.1 Let SOFDRA gel dry for 5 minutes after it is applied (Figure P). Keep clothing off the area while it dries. Note: It is okay to put your arms down.

- Do not put on clothing until gel has dried completely.
- Do not smoke or go near an open flame until the gel is dry. SOFDRA gel is flammable.



Figure P

10 Rinse and dry Applicator

10.1 Rinse off the Applicator with water (Figure Q).

Avoid touching the gel with your hands or fingers.

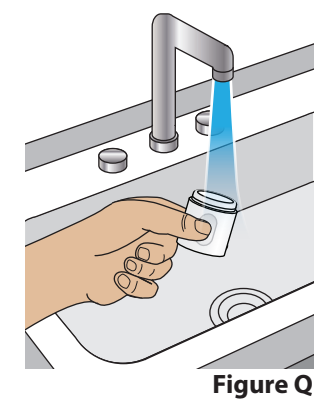


Figure Q

10.2 Pat the Applicator dry (Figure R).

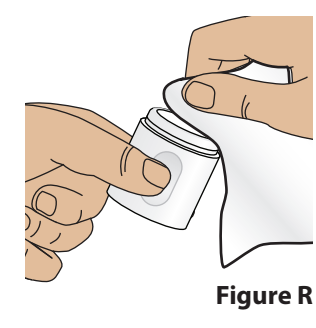


Figure R

11 Wash hands

11.1 Always wash your hands with soap and water right away after applying SOFDRA gel to avoid spreading any gel residue to any other parts of your body (Figure S).

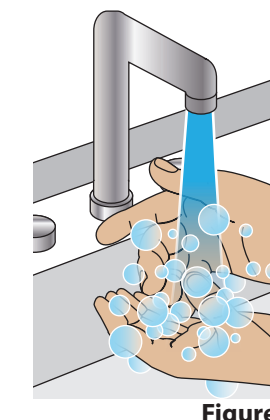


Figure S

12 Reassemble and store SOFDRA after use

12.1 Push the Applicator straight onto the Bottle, over the pump (Figure T).

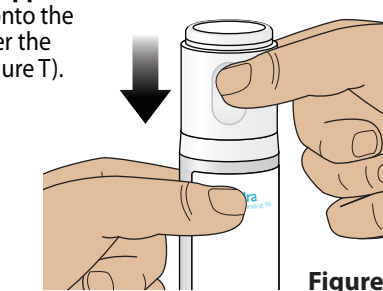


Figure T

12.2 Push the Blue Cap straight onto the top of the Applicator (Figure U).

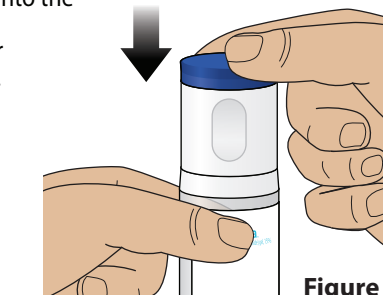


Figure U

13 Keep SOFDRA on skin for at least 8 hours

13.1 Wait at least 8 hours after applying SOFDRA before you shower or wash your underarms (Figure W).

Do not shower or wash your underarms for at least 8 hours after applying SOFDRA.



Figure W

Storage Information

Store SOFDRA upright at room temperature between 68°F to 77°F (20°C to 25°C) (Figure X)

Keep SOFDRA and all medicines out of reach of children.

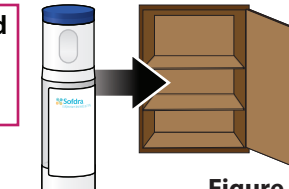


Figure X

Disposal Information

After applying 30 daily doses of SOFDRA gel (Figure Y), throw away the Blue Cap, Applicator, and Bottle into the household trash.

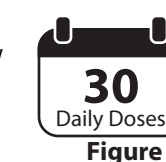


Figure Y

Additional Information

For additional information about how to apply SOFDRA, go to www.sofdra.com or call 1-866-763-6337

Manufactured For: Botnix SB Inc. Wayne, PA 19087

SOFDRA™ is a trademark of Botnix SB Inc.

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Issued: 2024-06-18