

PATIENT INFORMATION

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

Important information: SOFDRA is for use on the skin in the underarm area only. Do not apply SOFDRA to other parts of your body.

What is SOFDRA?

SOFDRA is a prescription anticholinergic medicine used on the skin (topical) to treat excessive underarm sweating (primary axillary hyperhidrosis) in adults and children 9 years of age and older.

It is not known if SOFDRA is safe and effective in children under 9 years of age.

Who should not use SOFDRA?

Do not use SOFDRA if you have certain medical conditions that can be made worse by taking an anticholinergic medicine such as:

- glaucoma
- severe ulcerative colitis or certain other serious bowel problems
- myasthenia gravis
- Sjogren's syndrome

Talk to your healthcare provider if you are not sure if you have a medical condition that can be made worse by taking an anticholinergic medicine.

Before using SOFDRA, tell your healthcare provider about all of your medical conditions, including if you:

- have prostate or bladder problems, or problems passing urine
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if SOFDRA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SOFDRA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with SOFDRA.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

SOFDRA may affect the way other medicines work causing side effects. **Especially tell your healthcare provider if you take anticholinergic medicines.**

Know the medicines you take. Keep a list of your medicines with you and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use SOFDRA?

- Use SOFDRA exactly as your healthcare provider tells you to use it.
- See the detailed **"Instructions for Use"** for directions about how to apply SOFDRA.
- **Apply SOFDRA 1 time a day at bedtime.**
- **Apply SOFDRA to clean, dry, intact skin of your underarm areas only.**
- Apply SOFDRA to both underarm areas using 1 pump for each underarm.
- **Do not** shower or wash underarms for at least 8 hours after applying SOFDRA.
- **Do not** use SOFDRA more than 1 time a day.
- **Do not** apply SOFDRA to broken skin.
- **Do not** cover the treated area with a plastic (occlusive) dressing.
- **Do not** apply SOFDRA if you have shaved your underarms or applied deodorant within the last 8 hours.
- **Do not** apply SOFDRA if you have exercised or showered or washed your underarms within the last 30 minutes.
- **Wash your hands with soap and water right away after you apply SOFDRA.** It is important that you wash your hands because the SOFDRA that is still on your hands can cause you to have blurred vision if you touch your eyes.
- Do not allow clothing to contact SOFDRA for 5 minutes after applying.
- **Do not touch your underarms after applying SOFDRA.**
- If you use too much SOFDRA, remove SOFDRA with soap and water, and call your healthcare provider or Poison Help line at 1-800-222-1222.

What should I avoid while using SOFDRA?

- SOFDRA may cause you to have blurred vision that is temporary. If you develop blurred vision, call your healthcare provider, stop using SOFDRA and do not drive, operate machinery, or do hazardous work until your vision is clear.
- **SOFDRA is flammable.** Avoid fire, flame, and smoking during and right after applying SOFDRA to your skin.

What are possible side effects of SOFDRA?

SOFDRA can cause serious side effects, including:

- **Urinary retention.** People who use SOFDRA may develop urinary retention. Symptoms of urinary retention may include:
 - difficulty urinating
 - urinating frequently
 - urination in a weak stream or drips
 - full bladder or difficulty emptying your bladder (distended bladder)If you develop these symptoms, stop using SOFDRA and call your healthcare provider right away.
- **Problems with control of your body temperature.** SOFDRA can cause you to have decreased sweating in areas of your body other than the underarm area which could cause you to become overheated and to develop heat illness. When in hot or very warm temperatures, watch for lack of sweating on your body and stop using SOFDRA if you develop lack of sweating on your body. Stop using SOFDRA and call your healthcare provider right away if you develop any of these symptoms of heat illness:
 - hot, red skin
 - decreased alertness or passing out (unconsciousness)
 - fast, weak pulse
 - fast, shallow breathing
 - increased body temperature (fever)
- **Blurred vision.** See “What should I avoid while using SOFDRA?”

The most common side effects of SOFDRA include:

- dry mouth
- blurred vision
- pain, redness, swelling, itching and irritation in the underarm area
- dilation of the pupils of your eyes (mydriasis)
- problems with urination

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

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

How should I store SOFDRA?

- Store SOFDRA upright at room temperature between 68°F to 77°F (20°C to 25°C).
- **SOFDRA is flammable.** Keep SOFDRA away from heat or flame.

Keep SOFDRA and all medicines out of the reach of children.

General information about the safe and effective use of SOFDRA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SOFDRA for a condition for which it was not prescribed. Do not give SOFDRA to other people, even if they have the same condition you have. You can ask your pharmacist or healthcare provider for information about SOFDRA that is written for healthcare professionals.

What are the ingredients in SOFDRA?

Active ingredient: sopipronium

Inactive ingredients: citric acid, dehydrated alcohol, hexylene glycol, hydroxypropyl cellulose, and isopropyl myristate.

Manufactured for:

Botanix SB Inc., Wayne, PA 19087

For more information, go to www.botanixpharma.sofdra.com or call 1-866-763-6337

This Patient Information has been approved by the U.S. Food and Drug Administration.

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