

Instructions for Use

XYOSTED™ Testosterone Enanthate Injection USP

Single-use.
For subcutaneous injection.
Administer one device weekly.

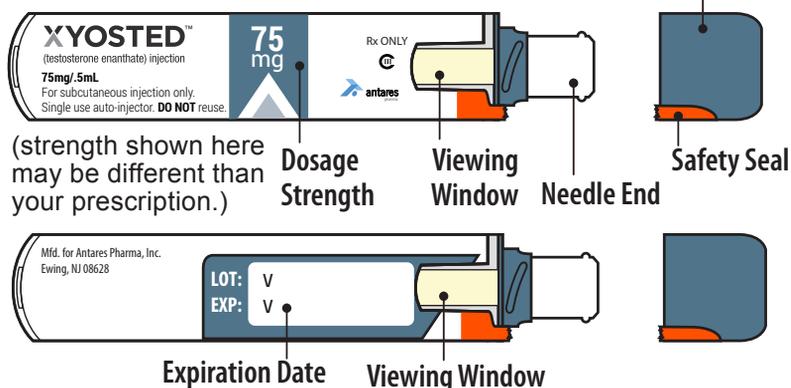
Read this Instructions for Use before you start using XYOSTED (ZYE-oh-sted) and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment.

Important Information about XYOSTED:

- Use XYOSTED exactly as your healthcare provider tells you to take it.
 - Inject XYOSTED only 1 time each week. Do not use XYOSTED every day.
 - Your healthcare provider will show you or your caregiver how to inject XYOSTED. You should not inject XYOSTED until you have been trained on the proper way to use it.
 - Check XYOSTED before you inject it. XYOSTED should be clear to light yellow in color and should be free of visible particles.
 - **Do not** use if the liquid is cloudy or if visible particles are present. You may see air bubble(s), this is normal.
 - **Do not** use XYOSTED if the safety seal is broken or if the Auto-Injector appears broken, damaged or changed in any way.
 - XYOSTED should be injected in the stomach (abdomen) area after cleaning the skin.
 - **Do not** inject XYOSTED within 2 inches of the belly button (navel).
 - **Do not** inject XYOSTED in any other areas of the body.
 - **Do not** inject XYOSTED in areas where the skin is tender, bruised, red, scaly, hard, or has scars or stretch marks.
- If you are not sure if XYOSTED was injected, or if you have a hard time giving the injection, do not inject another dose. Call your pharmacist or healthcare provider right away.

Figure 1: Description of Parts

Do not remove cap until ready to inject



If you need help or instructions, call:
1-844-996-7833

- ▶ Carefully read all steps before beginning injection.
- ▶ Injection process must be completed without interruption.

Supplies You Will Need

- ▶ 1 XYOSTED Auto-Injector
- ▶ 1 alcohol swab
- ▶ 1 cotton ball or gauze

Storage Conditions

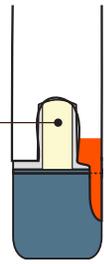
- Do not refrigerate or freeze.
- Protect from light.
- Use at room temperature.
- Store at 68° - 77° F (20° - 25° C).
- Keep XYOSTED and all medicines away from children.

Inspect Auto-Injector

- ▶ **Do not** remove Cap until ready to inject
- ▶ Inspect Auto-Injector for any visible damage. **Do not** use if it appears damaged or broken.
- ▶ Check the expiration date. **Do not** use if the expiration date has passed.
- ▶ Inspect the medicine through the Viewing Window; it should be clear to light yellow and free of visible particles (see Figure 2).

Do not use if the medicine is cloudy or if visible particles are present. You may notice an air bubble, this is normal.

Figure 2:



Select & Prep Injection Site

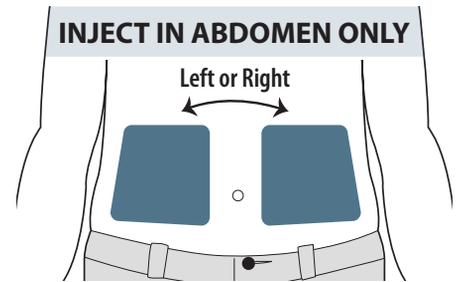
Wash your hands with soap and water.
Wipe the abdomen injection site with an alcohol swab.

Allow the site to dry on its own.
Do not fan or blow on the injection site.
Do not touch the site again before injecting.

Only use the left or right side of the abdomen (belly) for injection sites.
Do not use the area within 2 inches around your navel (belly button).
See Figure 3.

Do not use in areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars, tattoos, or stretch marks.

Figure 3:



Administering Injection

1 Remove Cap

Twist the Cap to remove (this will also break the red safety seal).
See Figure 4.

After the Cap is removed, a few drops of liquid may appear, this is normal.
The Auto-Injector should be used or discarded after the Cap is removed.
Do not re-Cap for later use.

⚠ Do not touch the Needle End of the Auto-Injector with your hand or fingers after the Cap is removed, doing so can cause injection and injury to your hands.

2 Position Auto-Injector

Gently squeeze the abdomen injection site to create a raised area and hold that area firmly until after the injection is complete (see Figure 5).



Place the Needle End of the Auto-Injector on the abdomen injection site.

Keep the Auto-Injector straight at a 90 degree angle to the abdomen injection site (see Figure 6).

Figure 4:

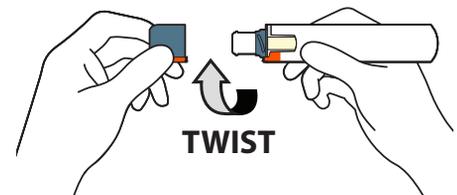
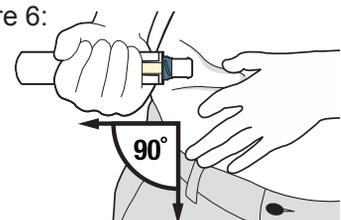


Figure 5:

**SQUEEZE
and
HOLD SITE**



Figure 6:



3 Inject & Hold Down

Firmly push the Auto-Injector down on the abdomen site and continue to hold it down after you hear the “CLICK” (see Figure 7).



While holding the XYOSTED Auto-Injector down, slowly count from 1 to 10 to allow all of the medicine to be delivered (see Figure 8).

Keep holding the XYOSTED Auto-Injector down for a total of 10 seconds even if your injection is complete and the viewing window turns orange sooner.

It is normal if there is slight bleeding from the site after injection. If this occurs, hold a cotton ball or gauze on the area for a few seconds. **Do not** rub the area.

4 Inspect Viewing Window

After injecting, inspect the Viewing Window. It should be orange, confirming the dose was administered (see Figure 9).

If the Viewing Window is not orange:

- **Do not** use another Auto-Injector.
- **Do not** attempt another injection.
- **Call** your healthcare provider or **1-844-996-7833** for assistance.

Record the abdomen injection site you used to help you remember to use a different site each time.

| Date | Abdomen Site Used |
|------|--|
| | LEFT <input type="checkbox"/> RIGHT <input type="checkbox"/> |
| | LEFT <input type="checkbox"/> RIGHT <input type="checkbox"/> |
| | LEFT <input type="checkbox"/> RIGHT <input type="checkbox"/> |
| | LEFT <input type="checkbox"/> RIGHT <input type="checkbox"/> |

Disposal After Injection



After completing your injection, dispose of the XYOSTED Auto-Injector and Cap in an FDA-cleared sharps disposal container immediately after use.

Do not dispose of the XYOSTED Auto-Injector in your household trash.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the proper way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Figure 7:

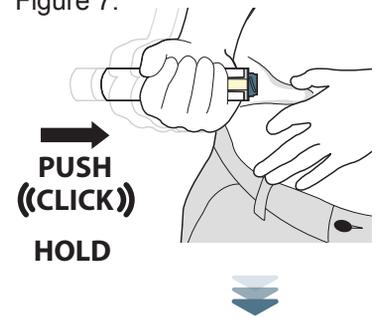


Figure 8:

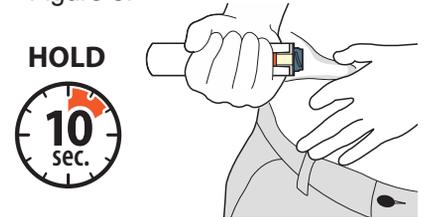
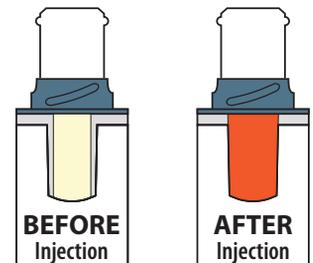


Figure 9:



This Instructions for Use has been approved by the U.S. Food and Drug Administration

LB-0118 V1

Manufactured for:
Antares Pharma, Inc.
Ewing, NJ 08628
09/2018