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OXYTROL[®] Oxybutynin Transdermal System

Revised: October 2012

Rx only

PATIENT INFORMATION

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OXYTROL (oxe-tröl) (oxybutynin transdermal system)

Read this Patient Information before you start taking OXYTROL and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is OXYTROL?

OXYTROL is a transdermal system (skin patch) for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. It delivers the active ingredient, oxybutynin, directly into your bloodstream through your skin.

Overactive bladder makes it hard to urinate (passing water). Overactive bladder can make you urinate more often (increased frequency) or make you feel the need to urinate often (urgency). Overactive bladder can also lead to accidental urine loss (leaking or wetting oneself). The active ingredient in OXYTROL, oxybutynin, is dissolved in the thin layer of adhesive that sticks the patch to your skin. OXYTROL delivers the medicine slowly and constantly through your skin and into your bloodstream for the 3 or 4 days that you wear the patch. OXYTROL contains the same active ingredient as oxybutynin tablets and syrup.

It is not known if OXYTROL is safe and effective in children.

Who should not use OXYTROL?

Do not use OXYTROL if you have the following medical conditions:

- **Urinary retention.** Your bladder does not empty or does not empty completely when you urinate.
- **Gastric retention.** Your stomach empties slowly or incompletely after a meal.
- **Uncontrolled narrow-angle glaucoma (high pressure in your eye).** Tell your doctor if you have glaucoma or a family history of glaucoma.
- **Allergy to oxybutynin or the inactive ingredients in OXYTROL.** If you are allergic to oxybutynin or any of the ingredients in OXYTROL. See the end of this leaflet for a complete list of ingredients in OXYTROL. If you have allergies to medical tape products or other skin patches, tell your doctor.

What should I tell my doctor before using OXYTROL?

Before you take OXYTROL, tell your doctor if you:

- have liver problems
- have kidney problems
- have problems emptying your bladder completely
- have a gastrointestinal obstruction (blockage in the digestive system)
- have ulcerative colitis (inflamed bowels)
- have gastric reflux disease or esophagitis (inflamed esophagus, the tube between your mouth and stomach)

- have Myasthenia Gravis (generalized muscle weakness)
- are pregnant or plan to become pregnant. It is not known if OXYTROL will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OXYTROL passes into your breast milk. You and your doctor should decide if you will take OXYTROL or breastfeed.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines and herbal supplements.

Using OXYTROL with certain other medicines may affect each other. Using OXYTROL with other medicines can cause serious side effects.

Especially tell your doctor if you take:

- medicines called “bisphosphonates” to treat osteoporosis
- medicines called “anticholinergics”

Ask your doctor or pharmacist for a list of these medicines if you are not sure if this is your medicine.

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

How should I use OXYTROL?

- Read the Instructions for Use at the end of this Patient Information Leaflet for information on the right way to use OXYTROL.
- Use OXYTROL exactly as your doctor tells you to use it.

- Put on a new patch of OXYTROL 2 times a week (every 3 to 4 days) according to your doctor's instructions.
- Choose a new skin site for each new patch application. You should not use the same skin site within 7 days.
- Wear the patch all the time until it is time to apply a new one.
- Wear only 1 patch of OXYTROL at a time.
- Try to change the patch on the same 2 days each week.
- Your package of OXYTROL has a calendar checklist printed on the back to help you remember your schedule. Mark the schedule you plan to follow. Always change OXYTROL on the 2 days of the week you mark on the calendar.
- Contact with water when you are bathing, swimming, showering or exercising will not change the way that OXYTROL works.

What should I avoid while using OXYTROL?

- You should not drink alcohol while using OXYTROL. It can increase your chance of getting serious side effects.
- OXYTROL can cause dizziness or blurred vision. **Do not** drive or operate machinery, or do other dangerous activities until you know how OXYTROL affects you.
- **Do not** put OXYTROL on areas that have been treated with oils, lotions, or powders that could keep the patch from sticking well to your skin. **Do not** expose the patch to sunlight. Wear your patch under clothing.

- Avoid rubbing the patch area during bathing, swimming, showering or exercising.

What are the possible side effects of OXYTROL? OXYTROL may cause serious side effects, including:

- **Inability to empty your bladder (urinary retention).** OXYTROL may increase your chances of not being able to empty your bladder if you have bladder outlet obstruction. Tell your doctor right away if you are unable to empty your bladder.
- **Increased risk of stomach problems in certain patients.** OXYTROL may cause stomach problems in patients who have a history of ulcerative colitis, intestinal atony, gastrointestinal reflux, or who are taking certain medicines called bisphosphonates.
- **Central nervous system effects.** OXYTROL can cause central nervous system effects including headache, dizziness, and sleepiness. Your doctor should monitor you for these effects after starting OXYTROL. See “*What should I avoid while using OXYTROL.*”
- **Swelling (angioedema).** The active ingredient in OXYTROL, oxybutynin can cause swelling around the eyes, lips, genitals, hands or feet. Some people who have taken oxybutynin medicines by mouth have had to be hospitalized. Stop using OXYTROL immediately and seek emergency treatment right away if you have any of these symptoms.
- **Skin hypersensitivity.** You may have skin changes where the patch was placed such as

itching, rash, or redness. Tell your doctor if these changes do not go away or bother you.

- **Worsening of myasthenia gravis.** OXYTROL can make symptoms worse in people who have myasthenia gravis. See “*What should I tell my doctor before using OXYTROL?*”

The most common side effects of OXYTROL include skin reactions where the patch is placed and dry mouth.

Since oxybutynin treatment may decrease sweating, you may overheat or have fever or heat stroke if you are in warm or hot temperatures.

Tell your doctor if you have any side effect that bothers you or that does not go away or if you have constipation.

These are not all the side effects of OXYTROL. For a complete list, ask your doctor or pharmacist.

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 OXYTROL?

- Store OXYTROL at 68°F to 77°F (20°C to 25°C).
- Do not store OXYTROL outside the sealed pouch.
- Keep OXYTROL patches in a dry place.

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

General information about the safe and effective use of OXYTROL.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information

Leaflet. Do not use OXYTROL for a condition for which it was not prescribed. Do not give OXYTROL to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information Leaflet summarizes the most important information about OXYTROL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about OXYTROL that is written for health professionals.

For more information, go to www.OXYTROL.com website or call 1-888-699-8765 (1-888-OXY-TROL).

What are the ingredients of OXYTROL?

Active Ingredient: oxybutynin

Inactive Ingredients: Flexible polyester/ethylene-vinyl acetate film, acrylic adhesive, triacetin, siliconized polyester film.

INSTRUCTIONS FOR USE

OXYTROL (oxe-tröl) (oxybutynin transdermal system)

Read this Instructions for Use that comes with your OXYTROL before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your doctor about your medical condition or treatment.

Where to apply OXYTROL:

- Put the patch on a clean, dry, and smooth (fold-free) area of skin on your abdomen (stomach area), hips or buttocks. **See Figure A.**
- Avoid your waistline area, since tight clothing may rub against the patch.
- The areas you choose should not be oily, damaged (cut or scraped), irritated (rashes) or have any other skin problems.
- **Do not** put OXYTROL on areas that have been treated with oils, lotions, or powders that could keep the patch from sticking well to your skin.
- When you put on a new patch, use a different area of skin from the most recent patch site. You may find it useful to change the site from one side of your body to the other.
- **Do not** use the same area for the patch for at least 1 week. You may choose to try different sites when using OXYTROL to find the sites that are most comfortable for you and where clothing will not rub against it.

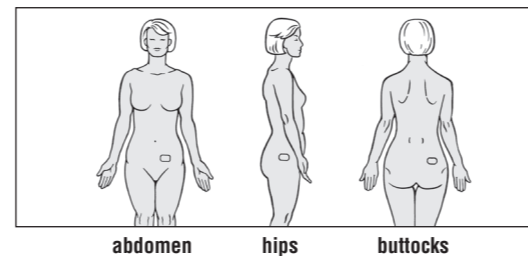


Figure A

How to apply OXYTROL:

Step 1.

- Each patch is sealed in its own protective pouch. **See Figure B.**
- When you are ready to put on your OXYTROL patch, tear open the pouch and remove the patch. **See Figure C.**

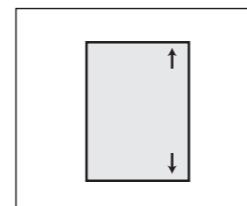


Figure B

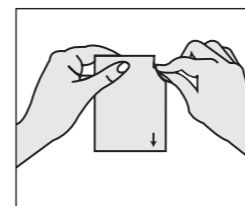


Figure C

Step 2.

- The sticky adhesive side of the patch is covered by 2 strips of overlapping protective liner. **See Figure D.**
- Remove the first piece of the protective liner and place the patch, adhesive side down, firmly onto the skin. **See Figure E.**

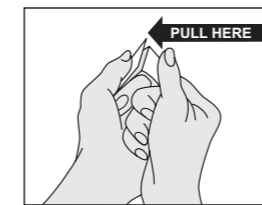


Figure D

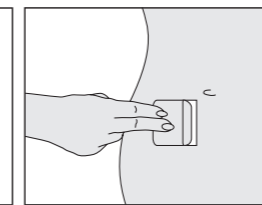


Figure E

Step 3.

- Bend the patch in half and gently roll the remaining part onto your skin using the tips of your fingers. As you roll the patch in place, the second piece of the protective liner should come off the patch. **See Figure F.**
- Apply firm pressure over the surface of the patch with your fingers to make sure the patch stays on. **See Figure G.**
- When putting on the patch, avoid touching the sticky adhesive side.
- Touching the adhesive may cause the patch to fall off early.
- Throw away the protective liners.
- If the patch partly or completely falls off, press it back in place and continue to follow your application schedule.
- If the patch does not stay on, throw it away. Put on a new patch on a different area of skin, and continue to follow your original application schedule.
- If you forget to change your patch after 3 or 4 days, remove the old patch, put on a new patch

in a different area of skin and continue to follow your original application schedule.

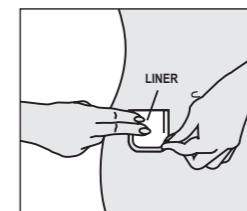


Figure F



Figure G

How to remove OXYTROL:

- When changing your OXYTROL patch, remove the old patch slowly and carefully to avoid damaging your skin.
- After the old patch is removed, fold it in half with the sticky sides together.
- **The patch will still contain some oxybutynin, throw the patch away so that it cannot be worn or swallowed by another person, child, or pet.**
- Gently wash the application site with warm water and a mild soap to remove any adhesive that stays on your skin after removing the patch.
- A small amount of baby oil may also be used to remove any adhesive remaining on your skin. Rings of adhesive that become dirty may require a medical adhesive removal pad that you can get from your pharmacist.
- Alcohol or other dissolving liquids (nail polish remover or other solvents) may cause skin irritation and should not be used.

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

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Distributed By:
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Revised: October 2012