

## Information for the Patient

# OXYTROL™

## Oxybutynin Transdermal System

Read this information carefully before you begin treatment. Read the information whenever you get more medicine, there may be something new. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about OXYTROL, ask your doctor. Only your doctor can determine if OXYTROL is right for you.

### What is OXYTROL?

OXYTROL is a transdermal system (skin patch) to treat overactive bladder. It delivers the active ingredient, oxybutynin, through your skin and into your bloodstream.

Overactive bladder makes it hard to control when you urinate (pass 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.

### 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.
- **Pregnancy or breastfeeding.** Tell your doctor if you are pregnant or breastfeeding. OXYTROL may not be right for you.
- **Allergy to oxybutynin or the inactive ingredients in OXYTROL.** If you need to know the inactive ingredients, ask your doctor or pharmacist. If you have allergies to medical tape products or other skin patches, tell your doctor.

If you have certain other medical conditions, use OXYTROL with caution. **Tell your doctor about all your medical conditions**, especially if you have any of the following:

- Liver disease
- Kidney disease
- Bladder obstruction (blockage)
- Gastrointestinal obstruction (blockage in the digestive system)
- Ulcerative colitis (inflamed bowels)
- Myasthenia gravis (nerve weakness)
- Gastric reflux disease or esophagitis (inflamed esophagus, the tube between your mouth and stomach)

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines and supplements. Some of them may cause problems if you take OXYTROL. Also, OXYTROL may affect how some of them work.

### What should I avoid while using OXYTROL?

Do not expose the patch to sunlight. Therefore, wear it under clothing.

### What are the possible side effects of OXYTROL?

You may see mild redness at the site when a patch is removed. This redness should disappear within several hours after removing the patch. If uncomfortable irritation or excessive itchiness continues, tell your doctor.

Oxybutynin may cause sleepiness or blurred vision, so be careful when driving or operating machinery. In addition, sleepiness may be increased by drinking alcohol (beer, wine or hard liquor).

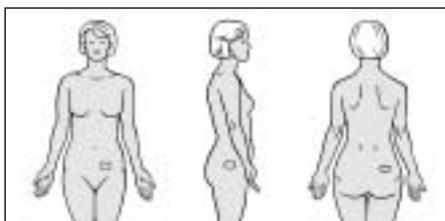
Since oxybutynin treatment may decrease sweating, you may overheat or have fever or heat stroke if you are in warm or hot temperatures.

The most common side effects of OXYTROL are skin reactions where the patch is put on. These include itching and redness. Other side effects include dry mouth, constipation, abnormal vision and headache. If you take other medicines that cause dry mouth, constipation, or sleepiness, OXYTROL can increase those effects.

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

### How should I use OXYTROL?

Put on a new patch of OXYTROL 2 times a week (every 3 to 4 days) according to your doctor's instructions. 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.

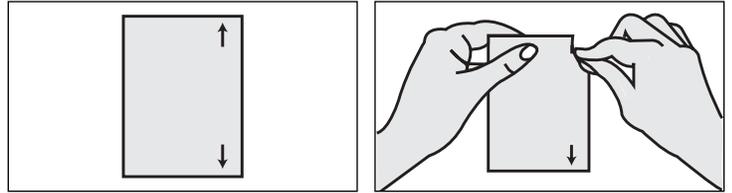


abdomen      hips      buttocks

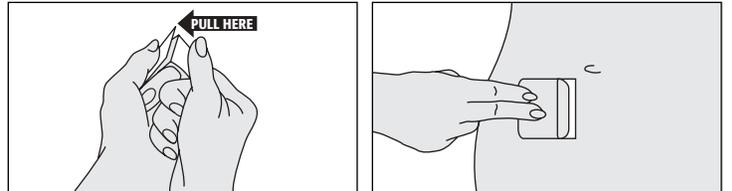
Put the patch on a clean, dry, and smooth (fold-free) area of skin on your abdomen (stomach area), hips or buttocks (as shown in the picture). Avoid your waistline area, since tight clothing may rub

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.**

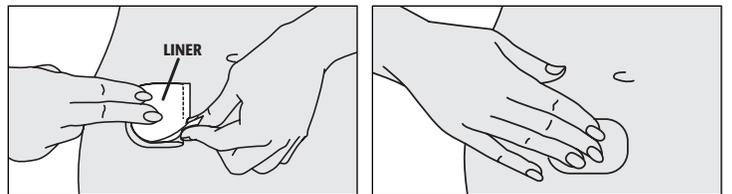
When you put on a new patch, use a different area of skin from the most recent patch site. You may find it useful to change the site from one side of your body to the other. Do not use the same area for the patch for at least 1 week. You may wish to try different locations when using OXYTROL to find the locations that are most comfortable for you and where clothing will not rub against it.



Each patch is sealed in its own protective pouch. When you are ready to put on the OXYTROL patch, tear open the pouch and remove the patch. Apply the patch to your skin right away. Do not keep or store the patch outside the sealed pouch.



The sticky adhesive side of the patch is covered by 2 strips of overlapping protective liner. Remove the first piece of the protective liner and place the patch, adhesive face down, firmly onto the skin.



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 move off the patch. Apply firm pressure over the surface of the patch with your fingers to make sure the patch stays on. 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.

Contact with water when you are bathing, swimming, showering or exercising will not change the way that OXYTROL works. However, try to avoid rubbing the patch area during these activities.

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. You should then put on a new patch in a different area, but 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 and continue to follow your original application schedule.

When changing OXYTROL, remove the old patch slowly and carefully to avoid damaging the skin. Once off, fold the patch in half with the sticky sides together. **Since the patch will still contain some oxybutynin, throw it away so that it cannot be accidentally worn or swallowed by another person, especially a child, or a pet.**

Gently washing the application site with warm water and a mild soap should 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 excess residue. 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.

Store at room temperature, 25°C (77°F). Temporary storage between 15° and 30°C (59°F to 86°F) is also permitted. Keep OXYTROL and all medications in a safe, secure place and out of the reach of children.

### General advice about OXYTROL

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not give OXYTROL to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about OXYTROL. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about OXYTROL that is written for health professionals. You can get more information about OXYTROL from the product information department at 1-888-OXY-TROL (1-888-699-8765) or by selecting patient information at the OXYTROL Website located at [www.OXYTROL.com](http://www.OXYTROL.com).



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Corona, CA 92880 USA

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