

Oxytrol®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details. [Include if applicable]

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine. [Include if applicable]

1. Why am I using Oxytrol®?

Oxytrol® contains the active ingredient Oxybutynin. Oxytrol® is used for the treatment for overactive bladder.

For more information, see Section [1. Why am I using Oxytrol®?](#) in the full CMI.

2. What should I know before I use Oxytrol®?

Do not use if you have ever had an allergic reaction to Oxytrol® or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Oxytrol®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Oxytrol® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Oxytrol®?

- One new OXYTROL® patch should be applied two times a week (every three to four days) according to your doctor's instructions. Wear only one patch of OXYTROL® at a time.

More instructions can be found in Section [4. How do I use Oxytrol®?](#) in the full CMI.

5. What should I know while using Oxytrol®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are using Oxytrol®.</p> <ul style="list-style-type: none"> ● If you become pregnant while you are being treated with this medicine, tell your doctor immediately ● Keep all of your doctor's appointments so that your progress can be checked.
Driving or using machines	<ul style="list-style-type: none"> ● This medicine may cause tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous
Drinking alcohol	<ul style="list-style-type: none"> ● Drinking alcohol may increase sleepiness
Looking after your medicine	<ul style="list-style-type: none"> ● Keep the patches in the original pack until it is time to use them. If you take the patches out of the pouch they will not keep well. ● Keep the pack in a cool dry place where the

	temperature stays below 25°C
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For more information, see Section [5. What should I know while using Oxytrol®?](#) in the full CMI.

6. Are there any side effects?

This medicine helps most people with overactive bladder, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Oxytrol®

Active ingredient(s): Oxybutynin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Oxytrol®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Oxytrol®.**

Where to find information in this leaflet:

- [1. Why am I using Oxytrol®?](#)
- [2. What should I know before I use Oxytrol®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Oxytrol®?](#)
- [5. What should I know while using Oxytrol®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Oxytrol®?

Oxytrol® contains the active ingredient Oxybutynin. Oxytrol® is a transdermal patch. **Oxytrol® is used in the treatment for 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 three or four days that you wear the patch.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is only available with a doctor's prescription.

Care should be taken when driving or operating machinery as this medicine may cause sleepiness or blurred vision.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

2. What should I know before I use Oxytrol®?

Warnings

Do not use Oxytrol® if:

- you are allergic to oxybutynin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

This medicine must not be used by a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

You must not use this medicine if you have (or have had) any of 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)
- Toxic megacolon (a very inflated large intestine)

- Uncontrolled narrow-angle glaucoma (high pressure in your eye)
- Severe ulcerative colitis (inflamed bowel)
- Myasthenia gravis (nerve weakness).

You must not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions
 - Liver disease
 - Kidney disease
 - Diarrhoea (especially in patients with ileostomy or colostomy)
 - Bladder obstruction (blockage)take any medicines for any other condition
 - Gastrointestinal obstruction (blockage in the digestive system)
 - Non-severe ulcerative colitis (inflamed bowel)
 - Prostatic hypertrophy (enlargement of the prostate gland)
 - Gastric reflux disease or oesophagitis (inflamed oesophagus, the tube between your mouth and stomach)
 - Hyperthyroidism,
 - Cardiovascular disease (including coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia and hypertension)
 - A neurological disorder (including autonomic neuropathy, cognitive impairment or Parkinson's disease)

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell him/ her before using Oxytrol®

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and OXYTROL® may interfere with each other.

These include:

- Other anticholinergic drugs (used to treat incontinence)
- Bisphosphonates (used to strengthen bone)

These medicines may be affected by OXYTROL® or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being treated with this medicine

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and OXYTROL® may interfere with each other.

These include:

- Other anticholinergic drugs (used to treat incontinence)
- Bisphosphonates (used to strengthen bone)

These medicines may be affected by OXYTROL® or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being treated with this medicine

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Oxytrol®.

4. How do I use Oxytrol®?

How much to take / use

- One new OXYTROL® patch should be applied two times a week (every three to four days) according to your doctor's instructions.
- Wear only one patch of OXYTROL® at a time
- Follow the instructions provided and use Oxytrol® until your doctor tells you to stop.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help

When to take / use Oxytrol®

- Try to change the patch on the same two days each week.
- Your box of OXYTROL® has a calendar checklist printed inside to help you remember your schedule.
- Mark the schedule you plan to follow. Always change OXYTROL® on the two days of the week you mark on your calendar.

Where to apply it

- Put the OXYTROL® 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 on the package instructions
- 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.

Do not expose the patch to sunlight.

Therefore, wear it under clothing. When you put on a new patch, use a different area of skin from the most recent patch site. Do not use the same area for the patch for at least one 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.

How to apply 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 two 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 tip 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 OXYTROL® works. However, try to avoid rubbing the patch 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.

How to remove it

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 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 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. If the adhesive becomes dirty you 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.

If you forget to use Oxytrol®

If you forget to change your patch after three or four days, remove the old patch, put on a new patch in a different area and continue to follow your original application schedule.

If you use too much Oxytrol®

If you think that you have used too much Oxytrol®, you may need urgent medical attention.

You should immediately:

- Remove the patch
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Overdosage with oxybutynin has been associated with anticholinergic effects including:

- Excitation of the nervous system
- Flushing and fever
- Dehydration
- Irregular heart beat (Cardiac arrhythmia)
- Vomiting
- Difficulty passing Urine (urinary retention)

As OXYTROL® is given to you as a single patch, it is very unlikely that you will receive an overdose. However, if you experience severe side effects, tell your doctor or nurse immediately.

5. What should I know while using Oxytrol®?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist you are using OXYTROL®.

If you become pregnant while you are being treated with this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are being given this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Remind any doctor, dentist or pharmacist you visit that you are using Oxytrol®.

Things you should not do

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Oxytrol® affects you.

Oxytrol® may cause tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol may increase sleepiness.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Oxybutynin treatment may decrease sweating

You may overheat or have fever or heat stroke if you are in warm or hot temperatures.

Looking after your medicine

- **Keep the patches in the original pack until it is time to use them.**

If you take the patches out of the pouch they will not keep well

- **Keep the pack in a cool dry place where the temperature stays below 25°C.**
- **Do not store OXYTROL® in the refrigerator or the freezer**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor or nurse as soon as possible if you do not feel well while you are using OXYTROL®.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● skin irritation including rash or slight redness and itching of the skin where the patch has been. This redness should disappear within several hours after removing the patch)● Constipation; Diarrhoea; Dysuria (difficulty urinating); Dry Mouth; Nausea; Reduced sweating; Flatulence● Fatigue or tiredness; Sleepiness or Drowsiness; Headache; Abdominal pain; Back pain; Blurred vision	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

These side effects are usually mild and short lived. The most common side effects of OXYTROL® are skin reactions where the patch is put on. These reactions include redness and itching. If uncomfortable irritation or excessive itchiness continues, tell your pharmacist or doctor.

If you take other medicines that cause dry mouth, constipation, or sleepiness, OXYTROL® can increase these effects.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• shortness of breath, wheezing or troubled breathing;• swelling of the face, lips, tongue or other parts of the body;• rash, itching or hives on the skin	<p>Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>You may need urgent medical attention (or hospitalisation).</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Oxytrol® contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">● Each OXYTROL® transdermal patch contains 36mg Oxybutynin and delivers approximately 3.9 mg of oxybutynin per day.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● triacetin● acrylic adhesive solution (containing 2-ethylhexyl acrylate, N-vinyl pyrrolidone and hexamethyleneglycol dimethacrylate polymer domains),● clear backing film of polyester / ethylene vinyl acetate (PET/ EVA), and

- | | |
|--|--|
| | <ul style="list-style-type: none">• siliconised polyester release liner (PET). |
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This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

Do not take this medicine if you are allergic to any of these ingredients.

What Oxytrol® looks like

Each OXYTROL® patch is rectangular shape, slightly opaque, and is 39 cm². Printed on each patch are the words "OXYTROL®3.9 mg/ day".

The patch is composed of three layers. Layer 1 is a backing film which protects the adhesive/drug layer. Layer 2 is the adhesive/drug layer. Layer 3 is a release liner made up of 2 polyester strips that should be peeled off and discarded prior to applying the patch.

Each box of OXYTROL® contains 8 patches (one month's treatment).

(Aust R 125489).

Who distributes Oxytrol®

Theramex Australia Pty Ltd

Level 22, 60 Margaret Street,

Sydney NSW 2000

1800 THERAMEX or 1800 843 726

This leaflet was prepared in June 2021.