Drug Facts

Active ingredient (in each patch [transdermal system])
Oxybutynin 3.9 mg/day

Purpose
Overactive bladder treatment

Use
- treats overactive bladder in women
- you may be suffering from overactive bladder if you have had 2 or more of the following symptoms for at least 3 months:
  - urinary frequency (the need to urinate more often than usual; typically more than 8 times in 24 hours)
  - urinary urgency (a strong need to urinate right away)
  - urge incontinence (leaking or wetting yourself if you cannot control the urge to urinate)
  - non-drug therapies may also help you (see the consumer information leaflet inside the package)

Warnings
For external use only

Frequent urination can also be caused by:
- urinary tract infections (UTI)
- diabetes
- early pregnancy
- other more serious conditions

If you think you might have one of these conditions, it is important to see your doctor before use.

Sleepiness, dizziness, confusion, and blurry vision may occur. Do not drive or operate machinery until you know how the patch affects you.

Do not use if you
- have any of these symptoms, which could be the sign of a UTI or other serious condition.

See your doctor as soon as possible if you have:
- pain or burning when urinating. These symptoms may also be accompanied by a fever or chills.
- blood in your urine
- unexplained lower back or side pain
- urine that is cloudy, or foul-smelling

- are male. Your symptoms may be due to a more serious condition.
- are under the age of 18. It is not known if it works or is safe in children.
- only experience accidental urine loss when you cough, sneeze or laugh, you may have stress
incontinence. This product will not work for that condition.

- have been told by a doctor you have urinary retention (are not able to empty your bladder)
- have been told by a doctor you have gastric retention (your stomach empties slowly after a meal)
- have glaucoma
- are allergic to oxybutynin

Ask a doctor before use if you have

- symptoms of diabetes, such as:
  - excessive thirst
  - extreme hunger
  - unexplained weight loss
  - liver or kidney disease

Ask a doctor or pharmacist before use if you are

- taking a prescription medication for overactive bladder
- taking any drugs that may cause sleepiness, dizziness, dry mouth, constipation or blurred vision
- taking certain antibiotics (for example, erythromycin, clarithromycin) or prescription antifungals (for example, ketoconazole, itraconazole)

When using this product

- you may have itching, rash or redness where the patch was placed
- drinking alcohol may increase sleepiness

Stop use and ask a doctor if

- you are not able to empty your bladder (urinary retention)
- condition worsens, or if new symptoms appear
- condition does not improve after 2 weeks of use
- you have an allergic reaction to this product
- if you have severe redness, itchiness or blistering at the site of application

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

women 18 years of age and older:

How to use the patch:

- open 1 pouch and apply patch immediately to a clean, dry and smooth area of skin on your abdomen, hips or buttocks. Do not put the patch on oily, damaged (cut or scraped), or irritated (rashes) skin.
- do not cut the patch into smaller pieces
- wear patch under clothing, do not expose the patch to sunlight
- wear only 1 patch at a time for 4 days in a row
- after 4 days, remove the used patch and apply a new one
- change the patch every 4 days for as long as you use this product
- each time you put on a new patch, change the place where you put it (i.e., abdomen, hips or buttocks)
- if a patch falls off and you cannot press it back onto your skin, use a new patch

How to dispose of a used patch:
when you take off a used patch, fold it in half with the sticky sides together
throw it away so that it cannot be worn or swallowed by another person, especially a child, or a pet

Other information
product comes in individual sealed pouches, do not use if pouch is torn or opened
store between 20° to 25° C (68° to 77° F)
protect from moisture and humidity
do not store outside the sealed pouch

Inactive ingredients
arylic adhesive, polyester/ethylene-vinyl acetate film, siliconized polyester film, and triacetin

Questions or comments?
Call toll-free 1-888-OXYTROL (1-888-699-8765) between 9:00 AM and 5:00 PM Eastern Standard Time, Monday through Friday

PRINCIPAL DISPLAY PANEL - Carton
© Actavis 2015 All rights reserved.
Made in USA
Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054 USA
OXYTROL is a registered trademark of Actavis, Inc.
1660615/Rev. 08/15
229949-00
NDC 52544-166-04
Full Prescription Strength
OXYBUTYNIN TRANSDERMAL SYSTEM 3.9 mg/day
Overactive Bladder Treatment
OXYTROL® FOR WOMEN
Relief from Overactive Bladder
1 Patch Treats for 4 Days/4 Nights
4 PATCHES (Transdermal Systems)
16- Day Supply
**Route of Administration**

**TRANSDERMAL**

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>OXYBUTYNIN (UNII: K9P6MC7092)</td>
<td>OXYBUTYNIN</td>
<td>3.9 mg in 1 d</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIACETIN (UNII: XHX3C3X673)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:52544-166-08</td>
<td>8 in 1 CARTON</td>
<td>01/01/2016</td>
<td>01/31/2020</td>
</tr>
<tr>
<td>2</td>
<td>NDC:52544-166-04</td>
<td>4 in 1 CARTON</td>
<td>01/01/2016</td>
<td>01/31/2020</td>
</tr>
<tr>
<td>3</td>
<td>NDC:52544-166-54</td>
<td>1 in 1 POUCH</td>
<td>01/01/2016</td>
<td>01/31/2020</td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA202211</td>
<td>01/01/2016</td>
<td>01/31/2020</td>
</tr>
</tbody>
</table>

### Labeler

- Actavis Pharma, Inc. (119723554)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actavis Laboratories UT, Inc.</td>
<td></td>
<td>079589880</td>
<td>MANUFACTURE(52544-166)</td>
</tr>
</tbody>
</table>

Revised: 12/2018