OXYTROL FOR WOMEN- oxybutynin patch
Allergan, Inc.

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
- 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 put the patch on skin with oils, lotions or powders because that could keep the patch from sticking to your skin.
- wear patch under clothing, do not expose the patch to sunlight
- do not cut the patch into smaller pieces
- 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

acrylic 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

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PRINCIPAL DISPLAY PANEL
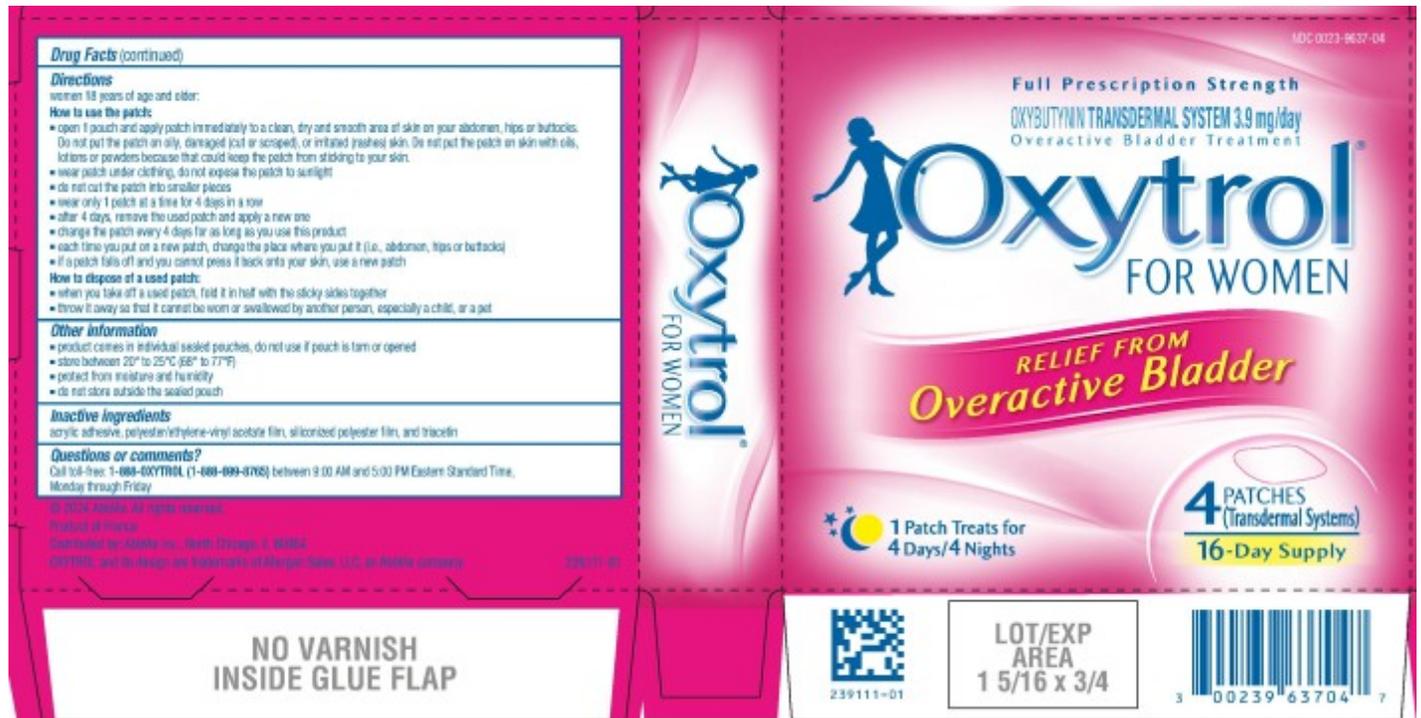
NDC 0023-9637-04
Full Prescription Strength
OXYBUTYNIN **TRANSDERMAL SYSTEM 3.9 mg/day**
Overactive Bladder Treatment
Oxytrol® FOR WOMEN

RELIEF FROM
Overactive Bladder
1 Patch Treats for
4 Days/4 Nights

4 PATCHES
(Transdermal Systems)
16-Day Supply

OXYTROL FOR WOMEN
oxybutynin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0023-9637
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBUTYNIN (UNII: K9P6MC7092) (OXYBUTYNIN - UNII:K9P6MC7092)	OXYBUTYNIN	3.9 mg in 1 d

Inactive Ingredients

Ingredient Name	Strength
TRIACETIN (UNII: XHX3C3X673)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0023-9637-04	16 in 1 CARTON	01/01/2016	
1		4 d in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:0023-9637-08	32 in 1 CARTON	10/01/2019	
2		4 d in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA202211	01/01/2016	

Labeler - Allergan, Inc. (144796497)

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Allergan, Inc.