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No Varnish
Inside Glue Flap

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Drug Facts (continued)

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 8:00 AM and 5:00 PM Central Standard Time, Monday through Friday

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Oxytrol® FOR WOMEN

NDC 11523-4322-4

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

LOT/EXP
Area
No Varnish

0 00000 00000 0

Drug Facts

Active ingredient (in each patch [transdermal system]) — **Purpose**

Oxybutynin 3.9 mg/day ..... 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.

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Drug Facts (continued)

- 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.

ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT
Helvetica Condensed
Variable horizontal scale adheres to 39 characters per inch

Drug Facts **-** 10 pt Helvetica Cnd. Bold Italic

Drug Facts (continued)
Drug Facts **-** 8.5 pt Helvetica Cnd. Bold Italic (continued) - 8.5 pt Helvetica Cnd.

Headings **-** 9 pt Helvetica Cnd. Bold Italic

Sub Heads -7 pt Helvetica Cnd. Bold

Text - 7 pt Helvetica Cnd, minimum leading 7.5

Square Bullets - 4.5 pt Zaph Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule

Hairline - .5 pt rule

(b) (4)

Reference ID: 3896456

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Drug Facts (continued)

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 8:00 AM and 5:00 PM Central Standard Time, Monday through Friday

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Oxytrol® FOR WOMEN

NDC 11523-4322-2

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

8 PATCHES (Transdermal Systems)

32-Day Supply

Oxytrol® FOR WOMEN

LOT/EXP
Area
No Varnish

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Drug Facts

Active ingredient (in each patch [transdermal system]) — **Purpose**

Oxybutynin 3.9 mg/day ..... 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.

LIFT FLAP

Drug Facts (continued)

- 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.

ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT
Helvetica Condensed
Variable horizontal scale adheres to 39 characters per inch

Drug Facts **-** 10 pt Helvetica Cnd. Bold Italic

Drug Facts (continued)
Drug Facts **-** 8.5 pt Helvetica Cnd. Bold Italic (continued) - 8.5 pt Helvetica Cnd.

Headings **-** 9 pt Helvetica Cnd. Bold Italic

Sub Heads -7 pt Helvetica Cnd. Bold

Text - 7 pt Helvetica Cnd, minimum leading 7.5

Square Bullets - 4.5 pt Zaph Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule

Hairline - .5 pt rule

(b) (4)

Reference ID: 3896456

ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT
Helvetica Condensed
Variable horizontal scale adheres to 39 characters per inch

Drug Facts - 10 pt Helvetica Cnd, Bold Italic

Drug Facts (continued)
Drug Facts - 8.5 pt Helvetica Cnd, Bold Italic
(continued) - 8.5 pt Helvetica Cnd,

Headings - 9 pt Helvetica Cnd, Bold Italic

Sub Heads -7 pt Helvetica Cnd, Bold

Text - 7 pt Helvetica Cnd, minimum leading 7.5

Square Bullets - 4.5 pt Zaph Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule

Hairline - .5 pt rule

(b) (4)

Reference ID: 3896456

Reference ID: 3896456

Drug Facts

Active ingredient (in each patch [transdermal system]) **Purpose**

Oxybutynin 3.9 mg/day ..... 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)
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Warnings

For external use only

Frequent urination can also be caused by:

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- **diabetes**
- **early pregnancy**
- **other more serious conditions**

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Drug Facts (continued)

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- protect from moisture and humidity
- do not store outside the sealed pouch

Inactive ingredients

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Questions or comments?

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14 PATCHES (Transdermal System)

56-Day Supply

1 Patch Treats for 4 Days/4 Nights

Oxytrol® FOR WOMEN

RELIEF FROM Overactive Bladder

Full Prescription Strength

OXYBUTYNIN TRANSDERMAL SYSTEM 3.9 mg/day

Overactive Bladder Treatment

NDC 11523-4222-3

ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT

Helvetica Condensed
Variable horizontal scale adheres to 39 characters per inch

Drug Facts - 10 pt Helvetica Cnd. Bold Italic

Drug Facts (continued)
Drug Facts - 8.5 pt Helvetica Cnd. Bold Italic (continued) - 8.5 pt Helvetica Cnd.

Headings - 9 pt Helvetica Cnd. Bold Italic

Sub Heads - 7 pt Helvetica Cnd. Bold

Text - 7 pt Helvetica Cnd, minimum leading 7.5

Square Bullets - 4.5 pt Zapf Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule

Hairline - .5 pt rule

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Important - Please Read

Oxytrol® for Women

Tips to Help Manage Your Overactive Bladder

You Are Not Alone - Overactive Bladder Affects Millions of Women

Many women believe that Overactive Bladder (OAB) is just another part of getting older. While you try not to let it slow you down, OAB can get in the way of your work, relationships, social life, exercise and even your sleep. It doesn't have to be that way. OAB is a treatable medical condition that you can do something about.

If Oxytrol® for Women doesn't help your OAB, talk with your healthcare provider.

Take Control of your OAB

There are several lifestyle changes you can try to help gain control over your Overactive Bladder (OAB) symptoms. Try one or all of these lifestyle changes, either alone or when using Oxytrol® for Women.

1. **Be Aware of what you Eat and Drink and Your Bathroom Habits**
   - **Watch the Foods you Eat and Drink:** Some food or drinks can make your OAB worse. These include coffee, tea, artificial sweeteners, caffeine, alcohol, soda/fizzy drinks, citrus fruits, food made with tomatoes, chocolate and spicy foods.
   - **Write It Down:** Keeping track of what you eat and drink and your trips to the bathroom for a few days in a "Bladder Diary" can help you to better understand your OAB by showing you some of the things that could be making your OAB worse.
   - **Drink Normal Amounts of Fluids:** Don't limit your water intake because you have OAB. Drink when you are thirsty. If waking up at night to use the bathroom is a problem, try to limit the amount of fluid you drink 2 to 3 hours before bedtime.

2. **Tips to help Retrain Your Bladder**
   - **Try Waiting (just a little):** Try to teach yourself to delay going to the bathroom for a little while, even when you feel an urge. At first, try to hold it for just a few minutes more. Gradually you can increase the time between bathroom visits.
   - **Follow a Schedule:** Try to follow a daily bathroom schedule. Instead of going whenever you feel the slightest urge, try to go at set times during the day. For example, you may decide to try to go every 2 hours, whether you feel you have to go or not. In time, you can try extending the time between bathroom visits.
   - **Go, and then Go Again:** When you go to the bathroom, don't get up right away when you finish. Wait for a few seconds and then try to make yourself go again.
   - **Strengthen your Bladder Muscles:** To locate the right muscles, imagine trying to stop the flow of urine. Quickly squeeze and release these muscles 3-4 times in a row. Repeat this exercise several times a day.

3. **Lifestyle Changes You Can Make**
   - **Maintain a healthy weight:** Excess weight can increase the pressure on your bladder and make your OAB worse.
   - **Stop Smoking:** Smoking can make your OAB worse.

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ATTACH LEGEND ON ALL DIGITAL MECHANICALS

MODIFIED FORMAT
Helvetica Condensed

Headings - 9pt Helvetica Cnd. Bold Italic

Sub Heads -6.5 pt Helvetica Cnd. Bold

Text - 6.5 pt Helvetica Cnd, minimum leading 7

Square Bullets - 4.5 pt Zaph Dingbats no compression

(b) (4)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
03/03/2016