Drug Facts

Active ingredient (in each patch)(clear)
Nicotine, 21 mg delivered over 24 hours

Active ingredient (in each patch)(clear)
Nicotine, 14 mg delivered over 24 hours

Active ingredient (in each patch)(clear)
Nicotine, 7 mg delivered over 24 hours

Active ingredient (in each patch)(opaque)
Nicotine, 21 mg delivered over 24 hours

Purpose
Stop smoking aid

Uses
reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.
Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

Ask a doctor before use if you have

• heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
• high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
• an allergy to adhesive tape or have skin problems because you are more likely to get rashes
• stomach ulcers or diabetes
• history of seizures

Ask a doctor or pharmacist before use if you are

• using a non-nicotine stop smoking drug
• taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.
When using this product

- if you have vivid dreams or other sleep disturbances remove this patch at bedtime

Stop use and ask a doctor if

- skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Keep out of reach of children and pets.

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together. Replace in pouch and discard.

Directions (Clear)

- if you are under 18 years of age, ask a doctor before use
- before using this product, read the enclosed User's Guide for complete directions and other information
- begin using the patch on your quit day
- if you smoke more than 10 cigarettes per day, use according to the following 10-week schedule:

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use one 21 mg patch/day</td>
<td>Use one 14 mg patch/day</td>
<td>Use one 7 mg patch/day</td>
</tr>
<tr>
<td>Weeks 1-6</td>
<td>Weeks 7-8</td>
<td>Weeks 9-10</td>
</tr>
</tbody>
</table>

- if you smoke 10 or less cigarettes per day, do not use STEP 1 (21 mg). Start with STEP 2 (14 mg) for 6 weeks, thenSTEP 3 (7 mg) for 2 weeks and then stop.
- steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chances of quitting successfully.
- apply one new patch every 24 hours on skin that is dry, clean and hairless. Save pouch for disposing of the patch after use.
- remove backing from patch and immediately press onto skin. Hold for 10 seconds.
- wash hands after applying or removing patch. Throw away the patch by folding sticky ends together. Replace in its pouch and discard. See enclosed User's Guide for safety and handling.
- you may wear the patch for 16 or 24 hours
- if you crave cigarettes when you wake up, wear the patch for 24 hours
- if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning
- the used patch should be removed and a new one applied to a different skin site at the same time each day
- do not wear more than one patch at a time
- do not cut patch in half or into smaller pieces
• do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
• it is important to complete treatment. If you feel you need to use the patch for a longer period to keep from smoking, talk to your health care provider.

**Directions (Opaque)**

• **if you are under 18 years of age, ask a doctor before use**
• before using this product, read the enclosed User's Guide for complete directions and other information
• stop smoking completely when you begin using the patch
• **if you smoke more than 10 cigarettes per day**, use according to the follow 10 week schedule:

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• if you smoke **10 or less cigarettes per day**, do not use **STEP 1 (21 mg)**. Start with **STEP 2 (14 mg)** for 6 weeks, then **STEP 3 (7 mg)** for 2 weeks and then stop.
• steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chances of quitting successfully.
• apply one new patch every 24 hours on skin that is dry, clean and hairless. Save pouch for disposing of the patch after use.
• remove backing from patch and immediately press onto skin. Hold for 10 seconds.
• wash hands after applying or removing patch. Throw away the patch by folding sticky ends together. Replace in its pouch and discard. See enclosed User's Guide for safety and handling.
• you may wear the patch for 16 or 24 hours
• if you crave cigarettes when you wake up, wear the patch for 24 hours
• if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning
• to avoid possible burns, remove patch before undergoing any MRI (magnetic resonance imaging) procedures
• the used patch should be removed and a new one applied to a different skin site at the same time each day
• do not wear more than one patch at a time
• do not cut patch in half or into smaller pieces
• do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
• it is important to complete treatment. If you feel you need to use the patch for a longer period to keep from smoking, talk to your health care provider.

**Other information**

• store at 20-25°C (68-77°F)

**Inactive ingredients (Clear)**

ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between clear
polyester backings

Inactive ingredients (Opaque)
ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between pigmented and clear polyester backings

Questions or comments?
call toll-free 1-800-834-5895

Principal Display Panel
NDC 0135-0194-02
NicoDerm
CQ
Nicotine Transdermal System 21 mg Delivered over 24 Hours
STOP SMOKING AID
CLEAR PATCH
EXTENDED RELEASE 24 HOURS
SMARTCONTROL TECHNOLOGY
STEP 1
21MG
IF YOU SMOKE MORE THAN 10 CIGARETTES A DAY, START WITH STEP 1
10 OR LESS CIGARETTES A DAY, START WITH STEP 2
ACTUAL SIZE
14 clear patches (2-week kit)
What is the NicoDerm CQ Patch and How is it Used?
NicoDermCQ is a small, nicotine-containing patch. When you put on a NicoDerm CQ patch, nicotine passes through the skin and into your body. NicoDermCQ is very thin and uses special material to control how fast nicotine passes through the skin. Unlike the sudden jolts of nicotine delivered by cigarettes, the amount of nicotine you receive remains relatively smooth throughout the 16 or 24 hour period you wear the NicoDermCQ patch. This helps to reduce cravings you may have for nicotine.

READ THE LABEL

• Not for sale to those under 18 years of age.
• Proof of age required.
• Not for sale in vending machines or from any source where proof of age cannot be verified.

Trademarks are owned by or licensed to the GSK group of companies.

For more information and for a FREE individualized stop smoking program, please visit www.nicodermcq.com or see inside for more details.

U.S. Patent No. 7,622,136
8,075,911
Read carton and enclosed User's Guide before using this product. Keep this carton and User's Guide. They contain important information.

**Includes Committed Quitters Program enrollment offer and User's Guide.**

**TO INCREASE YOUR SUCCESS IN QUITTING:**

1. You must be motivated to quit.
2. Complete the full treatment program, applying a new patch every day.
3. Use with a support program as described in the enclosed User's Guide.

**For your family's protection, NicoDermCQ patches are supplied in child resistant pouches. Do not use if individual pouch is open or torn.**

Manufactured by ALZA Corporation,
Vacaville, CA 95688 for
**GSK Consumer Healthcare**
Warren, NJ 07059
©2017 GSK or its licensor.

106192XA
NicoDerm
Nicotine Transdermal System 21 mg Delivered over 24 Hours
STOP SMOKING AID
CLEAR PATCH EXTENDED RELEASE 24 HOURS
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Manufactured by ALZA Corporation,
Nicotine Transdermal System 21 mg Delivered over 24 Hours
STOP SMOKING AID
OPAQUE PATCH
EXTENDED RELEASE 24 HOURS
SMARTCONTROL TECHNOLOGY

NEW DIRECTIONS FOR USE
- Keep Using if You Slip Up and Have a Cigarette
- Use Beyond 10 Weeks if Needed to Quit

STEP 1
IF YOU SMOKE MORE THAN 10 CIGARETTES A DAY, START WITH STEP 1
10 OR LESS CIGARETTES A DAY, START WITH STEP 2

ACTUAL SIZE
14 clear patches (2-week kit)

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NICODERM, NICODERM BURST DESIGN, CQ, COMMITTED QUITTERS, MAN ON STEP Device, SMARTCONTROL are trademarks owned by or licensed to the GSK group of companies.

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Manufactured by ALZA Corporation,
Vacaville, CA 95688 for
GlaxoSmithKline
Consumer Healthcare, L.P.
Moon Township, PA 15108
©2014 GSK
102838XB
### Product Information

**Product Type**
- HUMAN OTC DRUG

**Route of Administration**
- TRANSDERMAL

**Item Code (Source)**
- NDC: 0135-0194

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
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<tbody>
<tr>
<td>NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)</td>
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### Packaging

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<tr>
<th>#</th>
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<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
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<td>NDC:0135-0194-01</td>
<td>7 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NDC:0135-0194-02</td>
<td>14 in 1 CARTON</td>
<td></td>
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<tr>
<td>3</td>
<td>NDC:0135-0194-03</td>
<td>1 in 1 PACKAGE</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>NDC:0135-0194-05</td>
<td>14 in 1 CARTON</td>
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<tr>
<td>4</td>
<td>NDC:0135-0194-08</td>
<td>24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)</td>
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</tr>
<tr>
<td>2</td>
<td>NDC:0135-0194-07</td>
<td>24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)</td>
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</tr>
<tr>
<td>2</td>
<td>NDC:0135-0194-09</td>
<td>24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)</td>
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</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
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<tbody>
<tr>
<td>NDA</td>
<td>NDA020165</td>
<td>05/12/2011</td>
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**NICODERM CQ**

nicotine patch, extended release

**Product Information**
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<td>HUMAN OTC DRUG</td>
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<tbody>
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<td>NDC:0135-0195-02</td>
<td>14 in 1 CARTON</td>
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<tr>
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<tr>
<td>2</td>
<td>NDC:0135-0195-03</td>
<td>1 in 1 PACKAGE</td>
<td></td>
<td>05/12/2011</td>
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<tr>
<td>2</td>
<td></td>
<td>21 in 1 CARTON</td>
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</tr>
<tr>
<td>2</td>
<td></td>
<td>24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)</td>
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<tr>
<td>3</td>
<td>NDC:0135-0195-05</td>
<td>14 in 1 CARTON</td>
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<td>05/12/2011</td>
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<tr>
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<td>NDC:0135-0195-08</td>
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### NICODERM CQ

nicotine patch, extended release
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**Product Characteristics**

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<tr>
<th>Color</th>
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</table>

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

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