NICODERM CQ- nicotine patch, extended release
Haleon US Holdings LLC

Drug Facts

Active ingredient (in each patch)

Nicotine, 21 mg delivered over 24 hours

Active ingredient (in each patch)

Nicotine, 14 mg delivered over 24 hours

Active ingredient (in each patch)

Nicotine, 7 mg delivered over 24 hours

Purpose

Stop smoking aid

Use

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

- **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:

STEP 1	STEP 2	STEP 3
Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day
Weeks 1-6	Weeks 7-8	Weeks 9-10

- 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
- 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

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

21 mg

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?

NicoDerm *CQ* is a small, nicotine-containing patch. When you put on a NicoDerm *CQ* patch, nicotine passes through the skin and into your body. NicoDerm *CQ* 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 NicoDerm *CQ* 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.**

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, NicoDerm *CQ* patches are supplied in child resistant pouches. Do not use if individual pouch is open or torn.

Distributed by: **GSK Consumer Healthcare**

Warren, NJ 07059

Made in Ireland

1001595

Principal Display Panel

NDC 0135-0195-02

NicoDerm*CQ*

Nicotine Transdermal System 14 mg Delivered over 24 Hours

STOP SMOKING AID

CLEAR PATCH

EXTENDED RELEASE 24 HOURS

SMARTCONTROL TECHNOLOGY

STEP 2

14 mg

IF YOU SMOKE **10 OR LESS CIGARETTES** A DAY, START WITH **STEP 2**

MORE THAN 10 CIGARETTES A DAY, START WITH **STEP 1**

ACTUAL SIZE

14 clear patches (**2-week kit)**

The full course of treatment for STEP 2 is 2 or 6 weeks (depending on how many cigarettes you smoke per day). Read the enclosed User’s Guide for additional information.

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Distributed by: **GSK Consumer Healthcare**

Warren, NJ 07059

Made in Ireland

PA201227

Principal Display Panel

NDC 0135-0196-02

NicoDerm*CQ*

Nicotine Transdermal System 7 mg Delivered over 24 Hours

STOP SMOKING AID

CLEAR PATCH

EXTENDED RELEASE 24 HOURS

SMARTCONTROL TECHNOLOGY

STEP 3

7 mg

FOR USE **AFTER COMPLETING STEP 2**

ACTUAL SIZE

14 clear patches (**2-week kit)**

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Warren, NJ 07059

Made in Ireland

PA200699

NICODERM CQ

nicotine patch, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0194
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	21 mg in 24 h

Inactive Ingredients	
Ingredient Name	**Strength**
ETHYLENE-VINYL ACETATE COPOLYMER (40% VINYL ACETATE) (UNII: L5F16ZG4ZU)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:0135-0194-01	7 in 1 CARTON	05/12/2011	
1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0135-0194-02	14 in 1 CARTON	05/12/2011	
2		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:0135-0194-03	1 in 1 PACKAGE	05/12/2011	
3		21 in 1 CARTON		
3		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:0135-0194-05	14 in 1 CARTON	05/12/2011	
4	NDC:0135-0194-08	24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020165	05/12/2011	

NICODERM CQ

nicotine patch, extended release

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0195-02	14 in 1 CARTON	05/12/2011	
1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery		

1		Device/System (syringe, patch, etc.)		
2	NDC:0135-0195-03	1 in 1 PACKAGE	05/12/2011	
2		21 in 1 CARTON		
2		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:0135-0195-05	14 in 1 CARTON	05/12/2011	
3	NDC:0135-0195-08	24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020165	05/12/2011	

NICODERM CQ

nicotine patch, extended release

Product Information

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Route of Administration	TRANSDERMAL		

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Ingredient Name	Basis of Strength	Strength
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0135-0196-05	14 in 1 CARTON	05/12/2011	
2	NDC:0135-0196-08	24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020165	05/12/2011	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 5/2025 Haleon US Holdings LLC