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

NicoDermCQ

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.

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 <u>www.nicodermcq.com</u> 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

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1001595



Principal Display Panel

NDC 0135-0195-02

NicoDermCQ

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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PA201227



Principal Display Panel

NDC 0135-0196-02

NicoDermCQ

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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PA200699



NICODERM CQ					
nicotine patch, extended rele	ease				
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (S	ource)	NDC:01	35-0194
Route of Administration	TRANS DERMAL				
Active Ingredient/Active	Moietv				
•	ient Name	Ba	asis of Strengt	th	Strength
NICOTINE (UNII: 6M3C89ZY6R) (N			DTINE		mg in 24 h
Inactive Ingredients					
	Ingredient Name)			Strength
ETHYLENE-VINYL ACETATE CO	-		- 16ZG4ZU)		
HIGH DENSITY POLYETHYLENE	(UNII: UG00KM4WR7)				
Packaging					
# Item Code	Package Description		Marketing Start Date		larketing nd Date

	Marketin	g Application Number or Monograph	Marketing Start	Marketing End
Μ	larketin	g Information		
4	NDC:0135- 0194-08	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	
3		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3		21 in 1 CARTON		
3	NDC:0135- 0194-03	1 in 1 PACKAGE	05/12/2011	
2		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	
1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
1	NDC:0135- 0194-01	7 in 1 CARTON	05/12/2011	

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

NIC	CODER	м со					
nico	tine patch	, extended rele	ase				
	•						
Pro	oduct Inf	ormation					
Pro	duct Type	•	HUMAN OTC DRUG	Item Code	(Source)	NDC:013	35-0195
Rou	ite of Adm	ninistration	TRANS DERMAL				
Act	ive Ingre	edient/Active	Moiety				
			ent Name		Basis of Streng	th s	Strength
NICO	OTINE (UNII:		COTINE - UNII:6M3C89ZY6R				mg in 24 h
	Inactive Ingredients						
Ina	ctive Ing	gredients					
			Ingredient Name				Strength
ETH	YLENE-VIN	YL ACETATE COP	OLYMER (40% VINYL ACE		5F16ZG4ZU)		Strength
ETH	YLENE-VIN	YL ACETATE COP	•		5F16ZG4ZU)		Strength
ETH	YLENE-VIN	YL ACETATE COP	OLYMER (40% VINYL ACE		5F16ZG4ZU)		Strength
ETH HIGH	YLENE-VIN H DENSITY	YL ACETATE COP	OLYMER (40% VINYL ACE		5F16ZG4ZU)		Strength
ETH' HIGH	YLENE-VIN	YL ACETATE COP POLYETHYLENE (OLYMER (40% VINYL ACE		5F16ZG4ZU) Marketing Start Date		Strength arketing nd Date
етн нісн Рас #	YLENE-VIN H DENSITY ckaging Item	YL ACETATE COP POLYETHYLENE (OLYMER (40% VINYL ACE UNII: UG00KM4WR7)		Marketing		arketing

		Device/System (S	yringe, patch, etc.)					
~	NDC:0135-					05/12/2017		
2	0195-03	1 in 1 PACKAGE				05/12/2011		
2		21 in 1 CARTON	Tupo 2, Drofillad Drug D-1	ivon				
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		Type 2: Prefilled Drug Del yringe, patch, etc.)	ivery				
	0195-08	Device/System (S	yringe, patch, etc.)					
N	arkotin	g Informat	ion					
	Marketin	-	tion Number or Mond	ograph	Mar	keting Start	Ma	rketing End
	Category		Citation	3 1		Date		Date
NC	A	NDA020165			05/12/2	2011		
Р	roduct In	formation						
Pı	oduct Type)	HUMAN OTC DRUG	ltem Co	ode (S	ource)	NDC:	0135-0196
	oduct Type oute of Adn	e ninistration	HUMAN OTC DRUG TRANSDERMAL	ltem Co	ode (S	ource)	NDC:	0135-0196
R	oute of Adn	ninistration edient/Active	TRANS DERMAL Moiety	Item Co				
Ro Ao	oute of Adn	ninistration edient/Active Ingred	TRANS DERMAL		В	ource) asis of Streng DTINE		0135-0196 Strength 7 mg in 24 h
Ro Ao	oute of Adn	ninistration edient/Active Ingred	TRANSDERMAL Moiety ient Name		В	asis of Streng		Strength
Ra Aa	oute of Adn	ninistration edient/Active Ingred I: 6M3C89ZY6R) (NI	TRANSDERMAL Moiety ient Name		В	asis of Streng		Strength
Ra Aa	COTINE (UNIT	ninistration edient/Active Ingred I: 6M3C89ZY6R) (NI	TRANSDERMAL Moiety ient Name	5R)	В	asis of Streng		Strength
Ra Aa Ni In	COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII	ninistration edient/Active Ingred I: 6M3C89ZY6R) (NI gredients	TRANSDERMAL Moiety ient Name COTINE - UNII:6M3C89ZY6 Ingredient Nam POLYMER (40% VINYL AC	5R) ne	B	asis of Stren		Strength 7 mg in 24 h
Ra Aa Ni I m	COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII	ninistration edient/Active Ingred I: 6M3C89ZY6R) (NI gredients	TRANSDERMAL Moiety ient Name COTINE - UNII:6M3C89ZYC Ingredient Nam	5R) ne	B	asis of Stren		Strength 7 mg in 24 h
Ra Aa Ni In	COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII	ninistration edient/Active Ingred I: 6M3C89ZY6R) (NI gredients	TRANSDERMAL Moiety ient Name COTINE - UNII:6M3C89ZY6 Ingredient Nam POLYMER (40% VINYL AC	5R) ne	B	asis of Stren		Strength 7 mg in 24 h
R« A« NI In ET	COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII COTINE (UNII	ninistration edient/Active Ingred I: 6M3C89ZY6R) (NI gredients	TRANSDERMAL Moiety ient Name COTINE - UNII:6M3C89ZY6 Ingredient Nam POLYMER (40% VINYL AC	5R) ne	B	asis of Stren		Strength 7 mg in 24 h
Ra Aa NI In ET HI	COTINE (UNIT COTINE (UNIT) COTINE (edient/Active Ingred Ingred : 6M3C89ZY6R) (NI gredients YL ACETATE COP POLYETHYLENE (TRANSDERMAL Moiety ient Name COTINE - UNII:6M3C89ZY6 Ingredient Nam POLYMER (40% VINYL AC	5R) ne CETATE) (L	B	asis of Stren	gth	Strength 7 mg in 24 h
R(A(NI) In ET HI) P(#	Cotive Ingra Cotive Ingra Cotine (UNII active Ing HYLENE-VIN GH DENSITY Ackaging Item	edient/Active Ingred Ingred : 6M3C89ZY6R) (NI gredients YL ACETATE COP POLYETHYLENE (TRANSDERMAL Moiety ient Name COTINE - UNII:6M3C89ZY6 Ingredient Nam OLYMER (40% VINYL AC (UNII: UG00KM4WR7)	5R) ne CETATE) (L	B	asis of Streng DTINE 16ZG4ZU) Marketing	gth	Strength 7 mg in 24 h Strengt
R(A(NI) In ET HI HI 1	Cotive Ingra Cotive Ingra Cotive Ingra Cotive Ingra Active Ingra HYLENE-VIN GH DENSITY Ackaging Item Code NDC:0135-	edient/Active Ingred Ingred I: 6M3C89ZY6R) (NI Gredients IVL ACETATE COP POLYETHYLENE 14 in 1 CARTON 24 h in 1 PATCH;	TRANSDERMAL Moiety ient Name COTINE - UNII:6M3C89ZY6 Ingredient Nam OLYMER (40% VINYL AC (UNII: UG00KM4WR7)	5R) ne CETATE) (L	B	asis of Streng DTINE 16ZG4ZU) Marketing Start Date	gth	Strength 7 mg in 24 h Strengt
R(NI In ET HI #	Cotive Ingra Cotive Ingra Cotive Ingra Cotive Ingra Active Ingra HYLENE-VIN GH DENSITY Ackaging Item Code NDC:0135-	edient/Active Ingred Ingred I: 6M3C89ZY6R) (NI Gredients IVL ACETATE COP POLYETHYLENE 14 in 1 CARTON 24 h in 1 PATCH;	TRANSDERMAL Moiety ient Name COTINE - UNII:6M3C89ZYC Ingredient Nam OLYMER (40% VINYL AC (UNII: UG00KM4WR7) Package Description Type 2: Prefilled Drug Del	5R) ne CETATE) (L	B	asis of Streng DTINE 16ZG4ZU) Marketing Start Date	gth	Strength 7 mg in 24 h Strengt

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