

NICOTINE- nicotine patch
Rugby Laboratories

Nicotine Transdermal System

Drug Facts

Active ingredient Step One (in each patch)

Nicotine, 21 mg delivered over 24 hours

Active ingredient Step Two (in each patch)

Nicotine, 14 mg delivered over 24 hours

Active ingredient Step Three (in each patch)

Nicotine, 7 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.

Do not use

- If you continue to smoke, chew tobacco, use snuff, use nicotine gum, or use nicotine patch or other nicotine-containing products

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 skin problems because you are more likely to get rashes.
- stomach ulcer 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 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. Save pouch to use for patch disposal. Dispose of used patch by folding sticky ends together and putting in pouch.

Directions

- **If you are under 18 years of age, ask a doctor before use**
- Before using this product, read the enclosed self-help 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 the following schedule:

Weeks 1 thru 4	Weeks 5 and 6	Weeks 7 and 8
STEP 1 use one 21 mg patch/day	STEP 2 use one 14 mg patch/day	STEP 3 use one 7 mg patch/day

- If you smoke 10 or **less cigarettes per day**, start with **Step 2** for 6 weeks, then **Step 3** for 2 weeks and then stop
- Apply one new patch every 24 hours on skin that is dry, clean, and hairless
- Remove backing from patch and immediately press onto skin. Hold for 10 seconds.
- Wash hands after applying or removing patch. Save pouch to use for patch disposal. Dispose of used patch by folding sticky ends together and putting in pouch.
- The used patch should be removed and a new one applied to a different skin site at the same time each day

- If you have vivid dreams, you may remove the patch at bedtime and apply a new one in the morning
- 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
- Stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor.

Other information

Store at 20°-25°C (68°-77°F)

Inactive ingredients

acrylate adhesive, polyester, silicone adhesive

Questions or comments?

Call-1-844-562-7963

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. Use one patch daily according to directions.
3. It is important to complete treatment.
4. If you feel you need to use the patch for a longer period to keep from smoking, talk to your health care provider.
5. Use patch with a behavioral support program such as the one described in the enclosed booklet.

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

- **Not for sale to persons 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.**

Principal Display Panel - Step 1 - 21 mg Pouch Label

**Nicotine
Transdermal
System
21 mg**

STEP

ONE

Nicotine Transdermal System

21 mg delivered over 24 hours

STOP SMOKING AID

21 mg

DO NOT OPEN POUCH
UNTIL READY TO USE.

STEP ONE

DIRECTIONS: Apply one patch to a dry, clean, hairless portion of upper body or arms. Refer to Self-Help Guide for detailed directions.

DO NOT CUT PATCH. 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. Save pouch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in pouch. Store at 20°-25°C (68°-77°F).

DO NOT USE IF
INDIVIDUAL POUCH
IS OPEN OR TORN,
OR IF PATCH IS CUT.

Manufactured by:

AVEVA
DRUG DELIVERY SYSTEMS
A Hialeah Company

Miramar, FL 33025

4001305



Rev. 03/10

3

Principal Display Panel - Step 1 - 21 mg Carton Label

Rugby[®]

NDC 0536-5896-88

COMPARE TO THE ACTIVE INGREDIENT IN HABITROL^{®*}

Clear

Nicotine

Transdermal System

21 mg delivered over 24 hours

STOP SMOKING AID

21 mg

Includes Behavior Support Program with Self-Help Guide

STEP ONE

If you smoke MORE than 10 cigarettes per day: Start with Step 1

If you smoke 10 or LESS cigarettes per day: Start with Step 2

14 Patches

*Habitrol[®] is a registered trademark of Novartis Consumer Health, Inc.



Principal Display Panel - Step 2 - 14 mg Pouch Label

**Nicotine
Transdermal
System
14 mg**

**STEP
TWO**

**STEP
TWO**

**Nicotine
Transdermal
System**

14 mg delivered over 24 hours
STOP SMOKING AID

14 mg

**DO NOT OPEN POUCH
UNTIL READY TO USE.**

DIRECTIONS: Apply one patch to a dry, clean, hairless portion of upper body or arms. Refer to Self-Help Guide for detailed directions.

DO NOT CUT PATCH. 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. Save pouch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in pouch. Store at 20°-25°C (68°-77°F).

**DO NOT USE IF
INDIVIDUAL POUCH IS
OPEN OR TORN, OR IF
PATCH IS CUT.**

Manufactured by:



Miramar, FL 33025
4001304



3 0536-5895-330



Rev. 03/10

3

Principal Display Panel - Step 2 - 14 mg Carton Label

Rugby[®]

NDC 0536-5895-88

COMPARE TO THE ACTIVE INGREDIENT IN HABITROL^{®*}

Clear

Nicotine

Transdermal System

14 mg delivered over 24 hours

STOP SMOKING AID

14 mg

Includes Behavior Support Program with Self-Help Guide

STEP ONE

If you smoke MORE than 10 cigarettes per day: Start with Step 1

If you smoke 10 or LESS cigarettes per day: Start with Step 2

14 Patches

*Habitrol[®] is a registered trademark of Novartis Consumer Health, Inc.

Nicotine Transdermal System

7 mg delivered over 24 hours

STOP SMOKING AID

7 mg

DO NOT OPEN POUCH
UNTIL READY TO USE.

STEP THREE

DIRECTIONS: Apply one patch to a dry, clean, hairless portion of upper body or arms. Refer to Self-Help Guide for detailed directions.

DO NOT CUT PATCH. 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. Save pouch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in pouch. Store at 20°-25°C (68°-77°F).

DO NOT USE IF
INDIVIDUAL POUCH
IS OPEN OR TORN,
OR IF PATCH IS CUT.



Manufactured by:
AVEVA
Transdermal Systems
Miramar, FL 33025
4001303



Rev. 03/10

Principal Display Panel - Step 3 - 7 mg Carton Label

Rugby[®]

NDC 0536-5894-88

COMPARE TO THE ACTIVE INGREDIENT IN HABITROL^{®*}

Clear

Nicotine

Transdermal System

7 mg delivered over 24 hours

STOP SMOKING AID

7 mg

Includes Behavior Support Program with Self-Help Guide

STEP ONE

If you smoke MORE than 10 cigarettes per day: Start with Step 1

If you smoke 10 or LESS cigarettes per day: Start with Step 2

14 Patches

*Habitrol[®] is a registered trademark of Novartis Consumer Health, Inc.



NICOTINE

nicotine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-5894
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	7 mg in 24 h

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-5894-53	7 in 1 CARTON	10/20/1997	
1		1 h in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0536-5894-88	14 in 1 CARTON	10/20/1997	
2		1 h in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074612	10/20/1997	

NICOTINE

nicotine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-5895
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	14 mg in 24 h

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-5895-53	7 in 1 CARTON	10/20/1997	
1		1 h in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0536-5895-88	14 in 1 CARTON	10/20/1997	
2		1 h in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0536-5895-71	28 in 1 CARTON	10/20/1997	
3		1 h in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074612	10/20/1997	

NICOTINE

nicotine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-5896
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
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-5896-53	7 in 1 CARTON	10/20/1997	
1		1 h in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0536-5896-88	14 in 1 CARTON	10/20/1997	
2		1 h in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0536-5896-71	28 in 1 CARTON	10/20/1997	
3		1 h in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074612	10/20/1997	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Aveva Drug Delivery Systems		783982093	manufacture(0536-5894, 0536-5895, 0536-5896) , analysis(0536-5894, 0536-5895, 0536-5896)

Revised: 1/2024

Rugby Laboratories