

NICOTINE TRANSDERMAL SYSTEM- nicotine transdermal system patch, extended release
Apotex Corp.

Nicotine Transdermal System- nicotine patch, extended release

Drug Fact

Active ingredient(in each patch)

Step 1 - Nicotine, 21 mg delivered over 24 hours

Step 2 - Nicotine, 14 mg delivered over 24 hours

Step 3 - 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 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 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. Save pouch to use for patch disposal. Dispose of the used patches 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
- begin using the patch on your quit day
- if you smoke **more than 10 cigarettes per day**, use the following schedule below:

Weeks 1 thru 2	Weeks 5 and 6	Weeks 7 and 8
Step 1	Step 2	Step 3
Use one 21 mg patch/day	Use one 14 mg patch/day	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
- 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 the used patches 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
- 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 °C – 25 °C (68 °F – 77 °F)

Inactive ingredients

acrylate adhesive, polyester, silicone adhesive

Comments or Questions?

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.

PRINCIPAL DISPLAY PANEL - 14 mg CARTON

Nicotine Transdermal System

NDC No. 60505-7089-0

14 Patches

5500981

STEP 2

CLEAR
NICOTINE
TRANSDERMAL
SYSTEM PATCH

STOP SMOKING AID

14 mg delivered over 24 hours

24h

14 mg delivered over 24 hours

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

See self-help guide inside.

See bottom panel for lot number and expiration date.

NDC 60505-7089-0
compare to the active ingredient in Habitrol®

PLUS
Apothecare

CLEAR
NICOTINE TRANSDERMAL SYSTEM PATCH
STOP SMOKING AID

Includes Behavior Support Program with Self-help Guide

24h 14mg delivered over 24 hours

STEP 2

If you smoke more than 10 cigarettes per day: use after completing step 1. If you smoke 10 or less cigarettes per day: start with step 2.

14 mg / 14 patches

3 60505 70890 1

STEP 2

CLEAR
NICOTINE
TRANSDERMAL
SYSTEM PATCH

STOP SMOKING AID

24h

14mg delivered over 24 hours

• 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.

*This product is not manufactured or distributed by D.C. Ready, a Laboratory Ltd., distributor of Habitrol.

Distributed by:
Apothecare Corp,
Weston, Florida 33326

3002515
REV- 09/16

Drug Facts

Active ingredient (in each patch) Purpose
Nicotine, 14 mg delivered over 24 hours 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 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 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. Save pouch to use for patch disposal. Dispose of the used patches 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
• begin using the patch on your quit day
• if you smoke more than 10 cigarettes per day, use the following schedule below:

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
• 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 the used patches 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
• 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°C-25°C (68°F-77°F)

Inactive ingredients acrylate adhesive, polyester, silicone adhesive

Questions or comments? 1-844-962-7963

PRINCIPAL DISPLAY PANEL - 7 mg CARTON

Nicotine Transdermal System

NDC No. 60505-7088-0

14 Patches

5500R1

STEP 3

CLEAR
NICOTINE
TRANSDERMAL
SYSTEM PATCH

STOP SMOKING AID

7mg delivered over 24 hours

24h

7mg delivered over 24 hours

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

See self-help guide inside.

See bottom panel for lot number and expiration date.

NDC 60505-7088-0
compare to the active ingredient in Habitrol®

PLUS
Apothecare

CLEAR
NICOTINE
TRANSDERMAL
SYSTEM PATCH

STOP SMOKING AID

24h


7mg delivered over 24 hours

Includes Behavior Support Program with Self-help Guide

STEP 3

FOR USE AFTER
COMPLETING STEP 2

7mg /
14 patches



3 60505 70880 2

STEP 3

CLEAR
NICOTINE
TRANSDERMAL
SYSTEM PATCH

STOP SMOKING AID

24h

7mg delivered over 24 hours

- 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.

*This product is not manufactured or distributed by OTC, Reddy's Laboratories Ltd., distributor of Habitrol.

Distributed by:
Apothecare Corp.,
Weston, Florida 33326

3002514
REV- 09/18

Drug Facts

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 tapes or have 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 if your skin itches, 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 the used patches 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
begin using the patch on your quit day
if you smoke more than 10 cigarettes per day, use the following schedule below:

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
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 the used patches 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 lose 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°C-25°C (68°F-77°F)

Inactive ingredients acrylic adhesive, polyester, silicone adhesive

Questions or comments? 1-844-882-7863

PRINCIPAL DISPLAY PANEL- 21 mg CARTON

Nicotine Transdermal System

NDC No. 60505-7090-0

14 Patches

Drug Facts

Active ingredient (in each patch)
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.
a stomach ulcer or diabetes
a history of seizures

Ask a doctor or pharmacist before use if you are
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. Save pouch to use for patch disposal. Dispose of the used patches 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
begin using the patch on your quit day
if you smoke more than 10 cigarettes per day, use the following schedule below:

Weeks 1 and 2	Weeks 3 and 4	Weeks 5 and 6
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 8 weeks, then Step 3 for 2 weeks
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 the used patches 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 lose 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°C-25°C (68°F-77°F)

Inactive ingredients acrylate adhesive, polyester, silicone adhesive

Questions or comments? 1-844-862-7863

55809R1

STEP 1

CLEAR
NICOTINE
TRANSDERMAL
SYSTEM PATCH
STOP SMOKING AID

24h

21 mg delivered
over 24 hours

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

**See self-help
guide inside.**

See bottom panel for
lot number and
expiration date.

TO INCREASE YOUR SUCCESS IN QUITTING:

- You must be motivated to quit.
- Use one patch daily according to directions.
- 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.
- Use patch with a behavioral support program, such as the one described in the enclosed booklet.

NDC 60505-7090-0
*compare to the active
ingredient in Habitrol®*

PLUS
Apothecare

CLEAR
NICOTINE
TRANSDERMAL
SYSTEM PATCH
STOP SMOKING AID

24h 21mg delivered over 24 hours

Includes Behavior Support Program with Self-help Guide

STEP 1

*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.*

**21mg /
14 patches**

3 60503 70900 7

STEP 1

CLEAR
NICOTINE
TRANSDERMAL
SYSTEM PATCH
STOP SMOKING AID

24h

21mg delivered
over 24 hours

- 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.

*This product is not manufactured or distributed by Dr. Reddy's Laboratories Ltd., distributor of Habitrol.

Distributed by:
Apothec Corp.,
Weston, Florida 33326

3002516
REV- 09/18

NICOTINE TRANSDERMAL SYSTEM

nicotine transdermal system patch, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60505-7089
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
	NDC:60505			

1	NDC:60505-7089-0	14 in 1 CARTON	01/11/2019	
1		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	01/11/2019		

NICOTINE TRANSDERMAL SYSTEM				
nicotine transdermal system patch, extended release				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60505-7088	
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				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60505-7088-0	14 in 1 CARTON	01/11/2019	
1		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	01/11/2019		
NICOTINE TRANSDERMAL SYSTEM				
nicotine transdermal system patch, extended release				

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60505-7090
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:60505-7090-0	14 in 1 CARTON	01/11/2019	
1		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	01/11/2019	

Labeler - Apotex Corp. (845263701)

Registrant - Aveva Drug Delivery Systems (783982093)

Establishment

Name	Address	ID/FEI	Business Operations
Aveva Drug Delivery Systems Inc.		783982093	analysis(60505-7088, 60505-7089, 60505-7090) , manufacture(60505-7088, 60505-7089, 60505-7090)

Revised: 7/2023

Apotex Corp.