

000022

EFB 289



READ THE LABEL

Drug Facts

Active ingredient (in each patch)

Nicotine, 11 mg delivered over 24 hours.

Purpose

Stop smoking aid

Uses to reduce 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 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.
- a stomach ulcer or take insulin for diabetes. ■ skin problems or are allergic to adhesive tape, because you are more likely to get rashes

Ask a doctor or pharmacist before use if you are

- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted. ■ under 18 years of age

When using this product do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.

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, itching, welts or skin discoloration. ■ irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness, or rapid heartbeat. ■ you have vivid dreams or other sleep disturbances

Keep out of reach of children. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Throw away used patches carefully, using the enclosed Disposal Units. Follow the disposal instructions with each Disposal Unit.

Directions

- stop smoking completely before starting to use this product
- if you smoke 15 or less cigarettes per day, use one 11 mg patch each day for 6 weeks. ■ if you smoke 16 cigarettes or more per day, use one 22 mg patch each day for 6 weeks
- apply one new patch every 24 hours on skin that is dry, clean and hairless for six weeks. ■ refer to enclosed information and instruction leaflet before using this product
- wash hands after applying or removing a patch. Dispose of patch in the enclosed Disposal Unit. See enclosed instructions for safety and handling.
- 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 leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
- stop using Nicotine Transdermal System at the end of 6 weeks. If you still feel the need to use Nicotine Transdermal System talk to your doctor

Other information

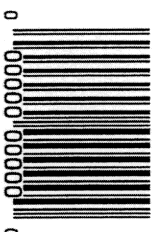
- do not open pouch until ready to use. ■ store between 20°C-25°C (68°F-77°F). ■ do not use if pouch is open or torn. ■ see side panel for expiration date

Inactive ingredients acrylate adhesive, aluminumized polyester, silicone adhesive

Questions If you have questions of a medical nature, please contact your doctor, pharmacist or health care provider. If you have questions concerning Nicotine Transdermal System, please call our toll free number 1-877-567-6690 for answers to frequently asked questions.

- 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.

Read carton and enclosed information and instruction leaflet before using this product. Keep the carton and information and instruction leaflet. They contain important information.



FORMAT: STANDARD

TYPE SIZES:

TITLE: 10 pt Helvetica Bold Italic
HEADINGS: 8 pt Helvetica Bold Italic
SUBHEADINGS: 6 pt Helvetica Bold
TEXT: 6 pt Helvetica Regular
LEADING: 6.5 pt
BULLET'S: 5 pt Square with
2 MS spacing between statements
TELEPHONE #: 6 pt Helvetica Bold
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

EXP. LOT NO.

44074 FA C2

CODE AREA

10/11/12/10

**Nicotine
Transdermal
System**

Stop Smoking Aid

HOW TO INCREASE YOUR SUCCESS IN QUITTING

1. Be motivated to quit the habit.
2. Closely follow the instructions outlined in the enclosed Information and Instruction Leaflet.
3. Apply a new patch every day.
4. Use the enclosed Action Guide for support in staying smoke free.

Keep out of reach of children. For your protection, the enclosed patches are contained in child-resistant pouches. Do not use if pouch is open or torn. Throw away used patches in the enclosed Disposal Units.

Nicotine Transdermal System

11 mg Delivered over 24 Hours

Stop Smoking Aid

For People Who Smoke 15 or Less Cigarettes a Day,
use one 11 mg patch each day for 6 weeks.

If You Smoke 16 or More Cigarettes a Day, use one 22 mg patch each day for 6 weeks.

11 mg
Refill Kit

Delivers **11 mg**
of Nicotine over 24 Hours

Child Resistant Disposal Units Enclosed

14 Patches
ONE WEEK SUPPLY

- Each box contains:
- 14 Patches
(two week supply)
 - Information and Instruction Leaflet
 - Action Guide for Staying Smoke-Free
 - Used Patch Disposal Units

PACKAGED BY
PERRIGO
ALLEGANY, MI 48010 U.S.A.

Nicotine Transdermal System

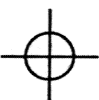
Stop Smoking Aid

What is Nicotine Transdermal System and how is it used?

Nicotine Transdermal System provides nicotine to your body, but does not contain the tar and carbon monoxide produced by cigarettes so it is not as dangerous as tobacco. By providing your body a level of nicotine lower than cigarettes, Nicotine Transdermal System helps you break the smoking habit and to overcome the withdrawal symptoms, including the craving for nicotine that occurs when you stop smoking.

EFB 290

000024



FORMAT: STANDARD

TYPE SIZES:
TITLE: 10 pt Helvetica Bold Italic
HEADINGS: 8 pt Helvetica Bold Italic
SUBHEADINGS: 6 pt Helvetica Bold
TEXT: 6 pt Helvetica Regular
LEADING: 6.5 pt
BULLETS: 5 pt Square with
2 M's spacing between statements
TELEPHONE #: 6 pt Helvetica Bold
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Drug Facts

Active ingredient (in each patch)

Nicotine, 11 mg delivered over 24 hours.

Purpose
Stop smoking aid

Use to reduce 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 other nicotine-containing products

Ask a doctor before use if you have

- heart disease, recent heart attack, or irregular heartbeat
- high blood pressure not controlled with medication
- skin problems or are allergic to adhesive tape, because you are more likely to get rashes
- a stomach ulcer or take insulin for diabetes

Ask a doctor or pharmacist before use if you are

- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted
- under 18 years of age

When using this product do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.

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, itching, welts or skin discoloration
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness, or rapid heartbeat
- you have vivid dreams or other sleep disturbances

Keep out of reach of children. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Throw away used patches carefully, using the enclosed Disposal Units. Follow the disposal instructions with each Disposal Unit.

Directions

- stop smoking completely before starting to use this product
- if you smoke 16 cigarettes or more per day, use one 22 mg patch each day for 6 weeks
- if you smoke 15 or less cigarettes per day, use one 11 mg patch each day for 6 weeks
- apply one new patch every 24 hours on skin that is dry, clean and hairless for six weeks
- refer to enclosed information and instruction leaflet before using this product
- wash hands after applying or removing a patch. Dispose of patch in the enclosed Disposal Unit. See enclosed instructions for safety and handling
- 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 leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
- do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
- stop using Nicotine Transdermal System at the end of 6 weeks. If you still feel the need to use Nicotine Transdermal System talk to your doctor

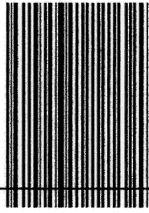
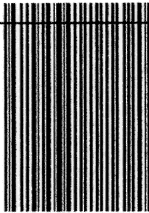
Other information

- do not open pouch until ready to use
- store between 20°C-25°C (68°F-77°F)
- do not use if pouch is open or torn
- see side panel for expiration date

Inactive ingredients: acrylic adhesive, aluminum polyester, silicone adhesive

Questions If you have questions of a medical nature, please contact your doctor, pharmacist or health care provider. If you have questions

concerning Nicotine Transdermal System, please call our toll free number 1-877-867-8690 for answers to frequently asked questions.



FA
Labeling: SE6-012 original
NDA No. 19-983 Rcd. 11-2-01
Reviewed by: OK AP 1417101

SEE OPENING INSTRUCTIONS ON BACK >
NICOTINE TRANSDERMAL SYSTEM
11mg Delivered over 24 Hours

STOP SMOKING AID

Each transdermal system contains 23.6mg nicotine and delivers 11mg over 24 hours.

Directions: See Information and Instruction Leaflet for application and disposal information. Apply patch immediately to the skin upon removal from pouch.

DO NOT USE IF POUCH IS OPEN OR TORN.

WARNING: Keep out of reach of children. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Throw away used patches carefully. Follow the disposal instructions with each Disposal Unit.

Code P004110 Rev. 12/98

PERRIGO
ALLIANCE, MI 48107 USA, CBT

SEE OPENING INSTRUCTIONS ON BACK >
NICOTINE TRANSDERMAL SYSTEM
11mg Delivered over 24 Hours

STOP SMOKING AID

Each transdermal system contains 23.6mg nicotine and delivers 11mg over 24 hours.

Directions: See Information and Instruction Leaflet for application and disposal information. Apply patch immediately to the skin upon removal from pouch.

DO NOT USE IF POUCH IS OPEN OR TORN.

WARNING: Keep out of reach of children. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Throw away used patches carefully. Follow the disposal instructions with each Disposal Unit.

Code P004110 Rev. 12/98

PERRIGO
ALLIANCE, MI 48107 USA, CBT

CUT POUCH TO OPEN

INSTRUCTIONS:

1. Open the pouch by cutting along the indicated line with scissors. Be careful not to cut the patch. If the patch is accidentally cut, discard it, do not use it.
2. Remove patch from pouch. Apply patch immediately to the skin upon removal from pouch following the directions in the Information and Instruction Leaflet.
3. After 24 hours remove the patch. Follow the disposal instructions with each Disposal Unit.

Storage: Do not store patch out of pouch. Store between 20°C-25°C (68°F-77°F).

4

CUT POUCH TO OPEN

INSTRUCTIONS:

1. Open the pouch by cutting along the indicated line with scissors. Be careful not to cut the patch. If the patch is accidentally cut, discard it, do not use it.
2. Remove patch from pouch. Apply patch immediately to the skin upon removal from pouch following the directions in the Information and Instruction Leaflet.
3. After 24 hours remove the patch. Follow the disposal instructions with each Disposal Unit.

Storage: Do not store patch out of pouch. Store between 20°C-25°C (68°F-77°F).

2

000020

000025

**Nicotine
Transdermal
System**

HOW TO INCREASE YOUR SUCCESS IN QUITTING

1. Be motivated to quit the habit.
2. Closely follow the instructions outlined in the enclosed information and instruction leaflet.
3. Apply a new patch every day.
4. Use the enclosed Action Guide for support in staying smoke free.

Keep out of reach of children. For your protection, the enclosed patches are contained in child-resistant pouches. Do not use if pouch is open or torn. Throw away used patches in the enclosed Disposal Units.

EFB 289
PT Size: 6.5PT

LOT NO.

EXP.

68410 FA C2

**CODE
AREA**

**Nicotine
Transdermal
System**

22 mg Delivered over 24 Hours

Stop Smoking Aid

For People Who Smoke 16 or More Cigarettes a Day,
use one 22 mg patch each day for 6 weeks.
If You Smoke 15 or Less Cigarettes a Day, use one 11 mg patch each day for 6 weeks.

**22 mg
Starter Kit**

Delivers 22 mg
of Nicotine over 24 Hours

Child Resistant Disposal Units Enclosed

7 Patches
ONE WEEK SUPPLY

Nicotine

**Transdermal
System**

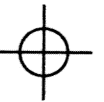
Stop Smoking Aid

What is Nicotine Transdermal System and how is it used?

Nicotine Transdermal System provides nicotine to your body, but does not contain the tar and carbon monoxide produced by cigarettes so it is not as dangerous as tobacco. By providing your body a level of nicotine lower than cigarettes, Nicotine Transdermal System helps you break the smoking habit and to overcome the withdrawal symptoms, including the craving for nicotine that occurs when you stop smoking.

- Each box contains:
- 7 Patches (one week supply)
 - Information and Instruction Leaflet
 - Action Guide for Staying Smoke-Free
 - Used patch Disposal Units
 - Audio Tape guide (for Starter Kit)

PACKAGED BY
PERHIGO
ALLERAN, MI 48010 USA



FORMAT: STANDARD

TYPE SIZES:
TITLE: 10 pt Helvetica Bold Italic
HEADINGS: 8 pt Helvetica Bold Italic
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2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Bold
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Drug Facts

Active ingredient (in each patch)

Nicotine, 22 mg delivered over 24 hours.

Purpose

Use to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking

Stop smoking aid

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 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.
- a stomach ulcer or take insulin for diabetes
- skin problems or are allergic to adhesive tape, because you are more likely to get rashes

Ask a doctor or pharmacist before use if you are

- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.
- under 18 years of age

When using this product do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.

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, itching, welts or skin discoloration
- you get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness, or rapid heartbeat
- you have vivid dreams or other sleep disturbances

Keep out of reach of children

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Throw away used patches carefully, using the enclosed Disposal Units. Follow the disposal instructions with each Disposal Unit.

Directions

- stop smoking completely before starting to use this product
- if you smoke 15 or less cigarettes per day, use one 11 mg patch each day for 6 weeks
- if you smoke 16 cigarettes or more per day, use one 22 mg patch each day for 6 weeks
- apply one new patch every 24 hours on skin that is dry, clean and hairless for six weeks
- wash hands after applying or removing a patch. Dispose of patch in the enclosed Disposal Unit. See enclosed instructions for safety and handling.
- 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 leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
- stop using Nicotine Transdermal System at the end of 6 weeks. If you still feel the need to use Nicotine Transdermal System talk to your doctor

Other information

- do not open pouch until ready to use
- store between 20°C-25°C (68°F-77°F)
- do not use if pouch is open or torn
- see side panel for expiration date

Inactive ingredients

acrylate adhesive, aluminumized polyester, silicone adhesive

Questions

If you have questions of a medical nature, please contact your doctor, pharmacist or health care provider. If you have questions concerning Nicotine Transdermal System, please call our toll free number 1-877-667-6690 for answers to frequently asked questions.

Not for sale to those under 18 years of age. Proof of age required.

FORMAT: STANDARD

TYPE SIZES:

TITLE: 10 pt Helvetica Bold Italic
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LEADING: 6.5 pt
BULLETS: 5 pt Square with
2 M's spacing between statements
TELEPHONE #: 6 pt Helvetica Bold
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

EXP. LOT NO.

68474 FA C2

CODE AREA

12/17/11 RR

**Nicotine
Transdermal
System**

Stop Smoking Aid

HOW TO INCREASE YOUR SUCCESS IN QUITTING

1. Be motivated to quit the habit.
2. Closely follow the instructions outlined in the enclosed information and instruction leaflet.
3. Apply a new patch every day.
4. Use the enclosed Action Guide for support in staying smoke free.

Keep out of reach of children. For your protection, the enclosed patches are contained in child-resistant pouches. Do not use if pouch is open or torn. Throw away used patches in the enclosed Disposal Units.

EFB 290

PT Size: 6.5PT

**Nicotine
Transdermal
System**

**22 mg Delivered over 24 Hours
Stop Smoking Aid**

For People Who Smoke 16 or More Cigarettes a Day,
use one 22 mg patch each day for 6 weeks.

If You Smoke 15 or Less Cigarettes a Day, use one 11 mg patch each day for 6 weeks.

**22 mg
Refill Kit**

Delivers 22 mg
of Nicotine over 24 Hours

Child Resistant Disposal Units Enclosed

14 Patches
TWO WEEK SUPPLY

- Each box contains:
- 14 Patches
(two week supply)
 - Information and Instruction Leaflet
 - Action Guide for Staying Smoke-Free
 - Used Patch Disposal Units

PACKAGED BY
PERRIGO
ALLEGAN, MI 49010 U.S.A.

**Nicotine
Transdermal**

What is Nicotine Transdermal System and how is it used?
Nicotine Transdermal System provides nicotine to your body, but
does not contain the tar and carbon monoxide produced by cigarettes.

Drug Facts

Active ingredient (in each patch)

Nicotine, 22 mg delivered over 24 hours.

Purpose

Uses to reduce 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

Ask a doctor before use if you have

- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate
- a stomach ulcer or take insulin for diabetes

Ask a doctor or pharmacist before use if you are

- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted
- under 18 years of age

When using this product do not smoke even when

Stop use and ask a doctor if

- you get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness, or rapid heartbeat
- you feel lightheaded caused by the patches not to away after four days, or if you spit sweats or you get a rash, itching, welts or skin discoloration
- irregular heartbeat or palpitations occur
- you have vivid dreams or other sleep disturbances

Directions

- **if you smoke 15 or less cigarettes per day, use one 22 mg patch each day for 6 weeks**
 ■ **if you smoke 16 cigarettes or more per day, use one 22 mg patch each day for 6 weeks**
 ■ **refer to enclosed information and instruction booklet before using this product**
- stop smoking completely before starting to use this product
- if you smoke 15 or less cigarettes per day, use one 1 mg patch each day for 6 weeks
 apply one new patch every 24 hours on skin that is dry, clean and hairless for six weeks
 wash hands after applying or removing a patch. Dispose of patch in the enclosed Disposal Unit. See enclosed instructions for safety and handling.
- 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 use patch on for more than 24 hours because it may irritate your skin and loosen strength after 24 hours
- do not use Micotine Transdermal System at the end of 6 weeks. If you still feel the same strength after 24 hours

Other information

- Reactive ingredients** acrylate adhesive, aluminumized polyester, silicone adhesive

Concerning Nicotine Tran

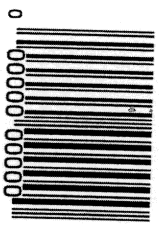
For more information, please call our toll free number 1-877-867-6690 for answers to frequently asked questions.

- Not for sale to those under 18 years of age. ■ Proof of age required.

...the following machines or manually source where proof of age cannot be verified.

**READ
THE LABEL**

Read carton and enclosed Information and Instruction Leaflet before using this product. Keep the carton and Information and Instruction Leaflet. They contain important information.



0...0000000

.....a very interesting and moving trial about you stop smoking.

המשרד לביטחון המדינה

Labeling: SE6-012 ^{FU} Original
NDA No. 19-483 Rcd. 11-2-01
Reviewed by: AR 12/17/01

SEE OPENING INSTRUCTIONS ON BACK
NICOTINE TRANSDERMAL SYSTEM
22mg Delivered over 24 Hours

STOP SMOKING AID

Each transdermal system contains 47.3mg nicotine and delivers 22mg over 24 hours.

Directions: See Information and Instruction Leaflet for application and disposal information. Apply patch immediately to the skin upon removal from pouch.

DO NOT USE IF POUCH IS OPEN OR TORN.

WARNING: Keep out of reach of children. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Throw away used patches carefully. Follow the disposal instructions with each Disposal Unit.

Code P002210 Rev. 12/98

PERRIGO
ALLEGAN, MI 49010 U.S.A. DIST.

SEE OPENING INSTRUCTIONS ON BACK
NICOTINE TRANSDERMAL SYSTEM
22mg Delivered over 24 Hours

STOP SMOKING AID

Each transdermal system contains 47.3mg nicotine and delivers 22mg over 24 hours.

Directions: See Information and Instruction Leaflet for application and disposal information. Apply patch immediately to the skin upon removal from pouch.

DO NOT USE IF POUCH IS OPEN OR TORN.

WARNING: Keep out of reach of children. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Throw away used patches carefully. Follow the disposal instructions with each Disposal Unit.

Code P002210 Rev. 12/98

PERRIGO
ALLEGAN, MI 49010 U.S.A. DIST.

CUT POUCH TO OPEN

INSTRUCTIONS:

1. Open the pouch by cutting along the indicated line with scissors. Be careful not to cut the patch. If the patch is accidentally cut, discard it, do not use it.
2. Remove patch from pouch. Apply patch immediately to the skin upon removal from pouch following the directions in the Information and Instruction Leaflet.
3. After 24 hours remove the patch. Follow the disposal instructions with each Disposal Unit.

Storage: Do not store patch out of pouch. Store between 20°C-25°C (68°F-77°F).

3

CUT POUCH TO OPEN

INSTRUCTIONS:

1. Open the pouch by cutting along the indicated line with scissors. Be careful not to cut the patch. If the patch is accidentally cut, discard it, do not use it.
2. Remove patch from pouch. Apply patch immediately to the skin upon removal from pouch following the directions in the Information and Instruction Leaflet.
3. After 24 hours remove the patch. Follow the disposal instructions with each Disposal Unit.

Storage: Do not store patch out of pouch. Store between 20°C-25°C (68°F-77°F).

1

INFORMATION AND INSTRUCTION LEAFLET

Nicotine Transdermal System

Stop Smoking Aid

Congratulations!

Your decision to stop smoking is one of the most important things you can do to improve your health. Becoming a non-smoker starts today. Your first step is to read through this entire information and instruction leaflet carefully.

It Is Hard To Quit

Nicotine Transdermal System helps smokers quit by reducing nicotine withdrawal symptoms. Many Nicotine Transdermal System users will be able to stop smoking for a few days, but often will start smoking again. Most smokers have to try to quit several times before they completely stop.

Your own chances of quitting smoking depend on how strongly you are addicted to nicotine, how much you want to quit and how closely you follow a quitting plan like the one described in this leaflet.

If you find you cannot stop, or if you start smoking again after using Nicotine Transdermal System, please talk to a health care professional who can help you find a program that may work better for you. Breaking this addiction doesn't happen overnight.

Because Nicotine Transdermal System provides some nicotine, Nicotine Transdermal System will help you stop smoking by reducing nicotine withdrawal symptoms such as nicotine craving, nervousness and irritability.

The information included with Nicotine Transdermal System will give you support as you become a non-smoker. It should be referred to often to answer common questions about Nicotine Transdermal System and give tips to help you stop smoking.

How Nicotine Transdermal System Works

Nicotine Transdermal System provides nicotine to your body, but does not contain the tar and carbon monoxide produced by cigarettes, so it is not as dangerous as tobacco. By providing your body a level of nicotine lower than cigarettes provide, Nicotine Transdermal System helps you break the smoking habit and to overcome the withdrawal symptoms, including the craving for nicotine, that occur when you stop smoking. However, this nicotine can still cause unpleasant effects such as headache, nausea, dizziness and upset stomach. Sometimes the patch will cause a skin reaction at the site of application.

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 other nicotine - containing products.

Ask a doctor before use if you:

- are under 18 years of age.
- have heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- have high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- have a stomach ulcer or take insulin for diabetes.
- are taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.
- are allergic to adhesive tape or have skin problems, because you are more likely to get rashes.

When using this product:

- do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.

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, itching, welts or skin discoloration.
- irregular heartbeat or palpitations occur.
- you get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness, or rapid heartbeat.
- you have vivid dreams or other sleep disturbances.

Remember

Nicotine Transdermal System is only for those who want to stop smoking. You should **not** smoke, chew tobacco, use snuff or use nicotine gum or other nicotine-containing products while using Nicotine Transdermal System, you may get a nicotine overdose. **Do not wear more than one patch at a time.**

Warning

Seizures have occurred in children who swallowed cigarettes. Children may have a similar reaction to nicotine patches.

Keep out of reach of children

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right way. Throw away used patches carefully, using the enclosed Disposal Units. Follow the disposal instructions with each Disposal Unit.

Getting Started

Check that you patch that is usually smoke day should use for 6 weeks. Six 16 or more mg patches one 22 mg patch. It is important that is appropriate may not receive prevent the withdrawal get more nicotine accustomed to overdose.

Choose A Quit

Choose your quit date. This is the day you stop using cigarettes. Nicotine Transdermal System is only for those who want to stop smoking. You should not smoke, chew tobacco, use snuff or use nicotine gum or other nicotine-containing products while using Nicotine Transdermal System, you may get a nicotine overdose. Do not wear more than one patch at a time.

Your decision to stop smoking is one of the most important things you can do to improve your health. Becoming a non-smoker starts today. Your first step is to read through this entire information and instruction leaflet carefully.

It Is Hard To Quit

Nicotine Transdermal System helps smokers quit by reducing nicotine withdrawal symptoms. Many Nicotine Transdermal System users will be able to stop smoking for a few days, but often will start smoking again. Most smokers have to try to quit several times before they completely stop.

Your own chances of quitting smoking depend on how strongly you are addicted to nicotine, how much you want to quit and how closely you follow a quitting plan like the one described in this leaflet.

If you find you cannot stop, or if you start smoking again after using Nicotine Transdermal System, please talk to a health care professional who can help you find a program that may work better for you. Breaking this addiction doesn't happen overnight.

Because Nicotine Transdermal System provides some nicotine, Nicotine Transdermal System will help you stop smoking by reducing nicotine withdrawal symptoms such as nicotine craving, nervousness and irritability.

The information included with Nicotine Transdermal System will give you support as you become a non-smoker. It should be referred to often to answer common questions about Nicotine Transdermal System and give tips to help you stop smoking.

System Works

Nicotine Transdermal System provides nicotine to your body, but does not contain the tar and carbon monoxide produced by cigarettes, so it is not as dangerous as tobacco. By providing your body a level of nicotine lower than cigarettes provide, Nicotine Transdermal System helps you break the smoking habit and to overcome the withdrawal symptoms, including the craving for nicotine, that occur when you stop smoking. However, this nicotine can still cause unpleasant effects such as headache, nausea, dizziness and upset stomach. Sometimes the patch will cause a skin reaction at the site of application.

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 other nicotine - containing products.

Ask a doctor before use if you:

- are under 18 years of age.
- have heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- have high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- have a stomach ulcer or take insulin for diabetes.
- are taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.
- are allergic to adhesive tape or have skin problems, because you are more likely to get rashes.

When using this product:

- do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.

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, itching, welts or skin discoloration.
- irregular heartbeat or palpitations occur.
- you get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness, or rapid heartbeat.
- you have vivid dreams or other sleep disturbances.

Remember

Nicotine Transdermal System is only for those who want to stop smoking. You should not smoke, chew tobacco, use snuff or use nicotine gum or other nicotine-containing products while using Nicotine Transdermal System, you may get a nicotine overdose. **Do not wear more than one patch at a time.**

Warning

Seizures have occurred in children who swallowed cigarettes. Children may have a similar reaction to nicotine patches.

Keep out of reach of children

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right way. Throw away used patches carefully, using the enclosed Disposal Units. Follow the disposal instructions with each Disposal Unit.

Getting Started

Check that you have chosen the nicotine patch that is best for you. Smokers who usually smoke 15 or fewer cigarettes a day should use one 11 mg patch each day for 6 weeks. Smokers who usually smoke 16 or more cigarettes a day should use one 22 mg patch each day for 6 weeks. It is important to use the nicotine patch that is appropriate for you otherwise you may not receive sufficient nicotine to prevent the withdrawal symptoms or may get more nicotine than your body is accustomed to, which could result in overdose.

Choose A Quit Date

Choose your quit date (it should be soon). This is the day you will quit smoking cigarettes entirely and begin using Nicotine Transdermal System to reduce your cravings for nicotine. Read all instructions before using Nicotine Transdermal System. Refer to them often to make sure you're using Nicotine Transdermal System correctly. Please refer to the "Action Guide for Staying Smoke Free" also.

Completing the full program as directed will increase your chances of quitting smoking.

Step 1: Do not remove the nicotine patch from its sealed pouch until you are ready to use it. Open the pouch by cutting along the indicated line with scissors. Be careful not to cut the patch. If the patch is accidentally cut, discard it, do not use it.



Figure 1

Step 2: Remove the patch from the pouch. A white protective liner covers the sticky side of the patch - the side that will be put on your skin. The liner has a pre-cut slit down the middle to help you remove it from the patch. With the white side facing you, pull half the liner away from the patch starting at the middle slit. Hold the patch at the edge (touch the sticky side as little as possible) and pull off the other half of the protective liner. Throw away this liner.

Step 3: Choose a non-hairy, clean, dry area of your body or the upper, outer part of your arm. Do not put a nicotine patch on skin that's very oily, burned, broken out, cut or irritated in any way. Apply the sticky side of the patch to the skin and press the patch firmly on the skin with the palm of your hand for about 10 seconds. Make sure it sticks well to the skin especially around the edges.

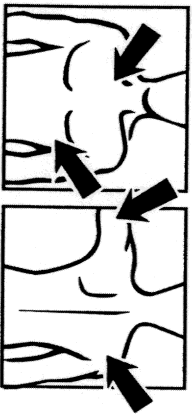


Figure 2

Step 4: When the patch is securely in place, wash your hands to remove any trace of nicotine. Nicotine on your hands could get into your eyes and nose, and cause stinging, redness, or more serious problems.

Step 5: After approximately 24 hours remove the patch carefully. If you apply the nicotine patch at about the same time each day, it will help you to remember when to put on a new nicotine patch. Choose a different place on your skin to apply the next patch. Do not return to a previously used skin site for at least one week. Do not leave a patch on for more than 24 hours because it may irritate your skin and because it loses strength after 24 hours.

Step 6: Carefully dispose of the used patch following the instructions with the disposal unit.

WARNING: KEEP OUT OF REACH OF CHILDREN AND PETS. Even used patches contain some nicotine and should be carefully disposed of.

How Long Should You Use Nicotine Transdermal System?

If you smoke approximately 15 cigarettes or less per day, use one 11mg Nicotine Transdermal System each day for 6 weeks. If you smoke approximately 16 or more cigarettes per day, use one 22mg Nicotine Transdermal System each day for 6 weeks. After completing the program if you still feel the need to use Nicotine Transdermal System, consult a health care professional.

If Nicotine Transdermal System Gets Wet

Water will not harm the nicotine patch you are wearing. You can bathe, swim, use a hot tub, or shower while you are wearing a nicotine patch.

If Your Nicotine Transdermal System Comes Off

If your Nicotine Transdermal System falls off, put on a new one. Remove the patch at your regular time to keep your schedule the same, or 24 hours after applying the replacement patch if you wish to change the time each day that you apply a new patch. Before putting on a new patch, make sure you select a non-hairy area which is not irritated and is clean and dry.

Storage Instructions

Keep Nicotine Transdermal System in its protective pouch until you are ready to use it. Store between 20°C - 25°C (68°F - 77°F). Remember, the inside of your car can reach temperatures much higher than this in the summer.

What To Watch For (Adverse Effects)

You should not smoke while using Nicotine Transdermal System. It is possible to get too much nicotine (an overdose), especially if you use a patch and smoke at the same time. Signs of an overdose would include nausea, bad headaches, dizziness, upset stomach, drooling, vomiting, diarrhea, cold sweat, blurred vision, difficulty with hearing, mental confusion and weakness. An overdose might cause you to faint.

Some people may have vivid dreams and sleep disturbances while using this product. Stop use and ask your doctor if this occurs.

If Your Skin Reacts To Nicotine Transdermal System

When you first put on a patch, mild itching, burning, or tingling is normal and should go away within an hour. After you remove the patch, the skin under the patch might be somewhat red. If you have skin redness caused by the patch that does not go away or if you get a skin rash, or if the skin under the patch becomes swollen or very red, see your doctor. Do not put on a new patch. You may be allergic to one of the components of the nicotine patch.

If you do become allergic to the nicotine in Nicotine Transdermal System, you could get sick from using cigarettes or other nicotine-containing products.

What To Do When Problems Occur

IF YOU NOTICE ANY WORRISOME SYMPTOMS OR PROBLEMS, TAKE OFF THE NICOTINE PATCH AND SEEK YOUR DOCTOR'S ASSISTANCE.

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Attachment
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857



NDA 19-983/S-012

Elan Pharmaceutical Research Corp.
Attention: Sharon Hamm, Pharm.D., R.Ph.
Senior Vice President, R&D Technical Operations
1300 Gould Drive
Gainesville, GA 30504

Dear Dr. Hamm:

We acknowledge receipt of your June 2, 1999 submission containing final printed labeling (FPL), in response to our December 23, 1998 letter approving your supplemental new drug application for Nicotine Transdermal System.

We have reviewed the labeling that you submitted in accordance with our December 23, 1998 letter, and we find it acceptable.

We request that the labeling for this drug product be revised within 180 days or at the time of the next printing, whichever comes first. The revisions are as follows:

1. The storage temperature designation (20° - 25° C (68° - 77° F)) on the outer carton labels is inconsistent with the storage temperature designation (20° C - 25° C (68° F - 77° F)) cited in our December 23, 1998 letter, and the other labeling (e.g., inner carton labels, pouch labels, and the information and instruction leaflets) for the product. The storage temperature designation should be corrected.
2. The phrase "Formerly available only by prescription" on the PDP for the 11 mg and 22 mg cartons must be deleted since more than 6 months of OTC marketing has occurred.
3. The location of the expiration date and lot number on the pouches should be identified.

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Final printed labeling that incorporates the revisions specified above may be included in your next annual report to this application. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that were made.

Please revise the labeling for this drug product in accordance with the provisions of the March 17, 1999 FEDERAL REGISTER document "Over-the-Counter Human Drugs; Labeling Requirements; Final Rule" (64 FR 13254) which has been incorporated into the regulations of 21 CFR 201.66. We remind you that the labeling of your product must be revised to reflect the Drug Facts format within the timeframes specified in the OTC labeling final rule. You may submit this revised labeling as a "Changes Being Effectuated" supplemental new drug application or as a change that may be described in your next annual report to this application.

If you have any questions regarding your application, please contact Daniel Keravich, RPh., M.Sc., M.B.A, Regulatory Project Manager, at (301) 827-2248.

Sincerely yours,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Attachment #2

NDA # 19-983

Elan Pharmaceutical Research Corporation
Attention: Sharon L. Hamm, Pharm.D., R.Ph.
Senior Vice President
R and D Technical Operations
1300 Gould Drive
Gainesville, GA 30504

Dear Ms. Hamm :

Please refer to your new drug application (NDA) for PROSTEP® (Nicotene transdermal system) transdermal patch 11mg/day and 22 mg/day.

We have recently completed a comprehensive review of the data relevant to the pregnancy-nursing warning on over-the-counter (OTC) nicotine replacement therapy (NRT) drug products (see enclosed Citizen Petition response). We ask that you replace your current pregnancy-nursing warning with the following so as to furnish adequate information for the safe and effective use of this drug.

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.

This warning should be the first warning under the Warnings heading in the Drug Facts labeling. This warning should be used in lieu of the general pregnancy and breast-feeding warning in 21 CFR 201.63(a) and the warning currently on OTC NRT drug products. Any other proposed warnings must be supported by data.

In addition we are asking that you provide additional data that may help further refine our understanding of the potential for reproductive harm or birth defects in humans exposed to NRT drug products, including the following:

- any additional information obtained in follow-up on adverse event reports in pregnant smokers submitted through the FDA MedWatch program, world wide safety monitoring, or directly reported to the company;
- consumer research studies that provide information on consumers' understanding of the benefits and risks of these products versus smoking during pregnancy ;

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- information on when and how these products are currently being utilized by physicians or other health care providers in pregnant smokers;
- information on the number of pregnant smokers who use these products, information on their attempts to quit smoking without NRT and the number of cigarettes smoked per day at the time they initiated NRT therapy;
- data on blood levels of nicotine in pregnant women for the specific NRT drug products relative to the nicotine levels associated with smoking (based on the number of cigarettes smoked at the start of NRT).

Please submit final printed labeling as a changes being effected supplemental application. Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL. Please individually mount ten of the copies on heavyweight paper or similar material.

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes being made.

If you propose a different warning, please submit draft labeling as a prior approval supplemental application. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

This supplemental application should be submitted within 180 days.

If you have any questions, contact Dan Keravich, R.Ph., M.S., M.B.A., Project Manager, at (301) 827-2222.

Sincerely,

(See appended electronic signature page)

Charles Ganley, M.D.
Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Linda Katz
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