

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20145/S006

FINAL PRINTED LABELING



SCHERING-PLOUGH RESEARCH INSTITUTE

NOTE: THIS LINE INDIC. VARNISH AREA

GLUE STRIP

FOR TRANSDERMAL USE ONLY.

See bottom panel for prescribing information.

Store at controlled room temperature 15°-30°C (59°-86°F). Do not refrigerate.

Patient: See instructions on back panel.

Key Pharmaceuticals, Inc. Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

Directions for Use:

1. Hold unit with brown lines facing you, in an up and down position.
2. Bend sides of unit away from you, then toward you until clear plastic backing "snaps" down middle.
3. Peel off one half of plastic backing.
4. Using the other half of plastic backing as a "handle", apply sticky side of the patch to upper arm or chest. Smooth down.
5. Fold back remaining side of the patch.
6. Grasp edge of plastic "handle" by stripe and pull it across the skin.

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician.

See bottom panel for prescribing information.

Place Pharmacy Label Here:

0.1 mg/hr (5 cm²)

R000000
00000000 12/94

DIE3629



NO VARNISH

NDC 0000-0000-00
Contents: 30 units

Nitro-Dur[®]
(nitroglycerin)
Transdermal Infusion System



Each unit contains 20 mg of nitroglycerin in acrylo-based polymer adhesives with a resinous cross-linking agent.

Rated release *in vivo* 0.1 mg/hr.

Caution: Federal law prohibits dispensing without prescription.

Key Pharmaceuticals, Inc. Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

0.1 mg/hr (5 cm²)

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician. See top panel for lot number and expiration date.

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FPO for UPC (80%)

DIE 3629

NO VARNISH

APPROVED
APR 12 1995

Obelings: HEP-110
NDA No: 20145 Rev'd 3/13/95
Reviewed by: Pauline
3/30/95



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NOTE: THIS LINE INDIC. VARNISH AREA

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Do not refrigerate.

R000000
00000000 12/94

Directions for Use:

1. Hold unit with brown lines facing you, in an up and down position.
2. Bend sides of unit away from you, then toward you until clear plastic backing "snaps" down middle.
3. Peel off one half of plastic backing.
4. Using the other half of plastic backing as a "handle", apply sticky side of the patch to upper arm or chest. Smooth down.
5. Fold back remaining side of the patch.
6. Grasp edge of plastic "handle" by stripe and pull it across the skin.

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician.

See bottom panel for prescribing information.

Place Pharmacy Label Here:

0.2 mg/hr (10 cm²)

Key Pharmaceuticals, Inc.
Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

Patent: See instructions on back panel.

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician. See top panel for lot number and expiration date.

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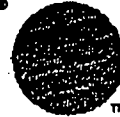


DIE
3629

DIE3829



Nitro-Dur[®]
(nitroglycerin)
Transdermal Infusion System



NDC 0000-0000-00
Contents: 30 units

Each unit contains 40 mg of nitroglycerin in acrylic-based polymer adhesives with a resinous cross-linking agent.

Rated release *in vivo* 0.2 mg/hr.

Caution: Federal law prohibits dispensing without prescription.

Key Pharmaceuticals, Inc.
Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

0.2 mg/hr (10 cm²)

NO VARNISH

NO VARNISH

APPROVED
APR 12 1995

Reviewed by: _____

Labeling: TR-20-110
NDA No: 20-145 Rec'd: 3/3/95

NOTE:
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Patient: See instructions on back panel.

KEY
Key Pharmaceuticals, Inc.
Kenilworth, NJ 07033 USA
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DIE3630

NO VARNISH

NDC 0000-0000-00
Contents: 30 units

Nitro-Dur[®]

(nitroglycerin)
Transdermal Infusion System.



Each unit contains 60 mg of nitroglycerin in acrylic-based polymer adhesives with a resinous cross-linking agent.

Rated release *in vivo* 0.3 mg/hr.

Caution: Federal law prohibits dispensing without prescription.

KEY Key Pharmaceuticals, Inc.
Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

0.3
mg/hr
(15 cm²)

- Directions for Use:**
1. Hold unit with brown lines facing you, in an up and down position.
 2. Bend sides of unit away from you, then toward you until clear plastic backing "snaps" down middle.
 3. Peel off one half of plastic backing.
 4. Using the other half of plastic backing, as a "handle", apply sticky side of the patch to upper arm or chest. Smooth down.
 5. Fold back remaining side of the patch.
 6. Grasp edge of plastic "handle" by stripe and pull it across the skin.
- Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician.
See bottom panel for prescribing information.

Place Pharmacy Label Here:

0.3 mg/hr (15 cm²)

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician.
See top panel for lot number and expiration date.

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FPO for UPC
(80%)

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See bottom panel for prescribing information.
Store at controlled room temperature 15°-30°C (59°-86°F).
Do not refrigerate.

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DIE 3630

NO VARNISH

APPROVED
APR 12 1995

Reviewed by: Burd
3/30/95
NDA No. 20-145 Rev. 3/95

NOTE:
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Patent: See instructions on back panel.

KEY
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World leader in drug delivery systems.

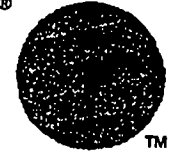
DIE3630

NO VARNISH

NDC 0000-0000-00
Contents: 30 units

Nitro-Dur[®]

(nitroglycerin)
Transdermal Infusion System



Each unit contains 80 mg of nitroglycerin in acrylio-based polymer adhesives with a resinous cross-linking agent.
Rated release *in vivo* 0.4 mg/hr.
Caution: Federal law prohibits dispensing without prescription.

0.4
mg/hr
(20 cm²)

KEY Key Pharmaceuticals, Inc.
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World leader in drug delivery systems.

Directions for Use:

1. Hold unit with brown lines facing you, in an up and down position.
2. Bend sides of unit away from you, then toward you until clear plastic backing "snaps" down middle.
3. Peel off one half of plastic backing.
4. Using the other half of plastic backing as a "handle", apply sticky side of the patch to upper arm or chest. Smooth down.
5. Fold back remaining side of the patch.
6. Grasp edge of plastic "handle" by stripe and pull it across the skin.

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician.
See bottom panel for prescribing information.

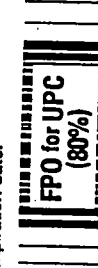
Place Pharmacy Label Here:

0.4 mg/hr (20 cm²)

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00000000 12/94

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician.
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DIE
3630

NO VARNISH



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FOR TRANSDERMAL USE ONLY.

See bottom panel for prescribing information.

Store at controlled room temperature 15°-30°C (59°-86°F).

Do not refrigerate.

12 1995

APPROVED

Labeling: H-D-110
NDA No: 20145 Rev'd 5/3/95
Reviewed by: [Signature] / [Signature]
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FOR TRANSDERMAL USE ONLY.

See bottom panel for prescribing information.

Store at controlled room temperature 15°-30°C (59°-86°F). Do not refrigerate.

Patient: See instructions on back panel.

Key Pharmaceuticals, Inc.
Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

Directions for Use:

1. Hold unit with brown lines facing you, in an up and down position.
2. Bend sides of unit away from you, then toward you until clear plastic backing "snaps" down middle.
3. Peel off one half of plastic backing.
4. Using the other half of plastic backing as a "handle", apply sticky side of the patch to upper arm or chest. Smooth down.
5. Fold back remaining side of the patch.
6. Grasp edge of plastic "handle" by stripe and pull it across the skin.

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician.

See bottom panel for prescribing information.

Place Pharmacy Label Here:

0.6 mg/hr (30 cm²)

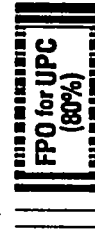
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DIE3830



Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician. See top panel for lot number and expiration date.

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FPO for UPC (80%)

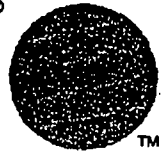
DIE
3630

APR 12 1995

NO VARNISH

NDC 0000-0000-00
Contents: 30 units

Nitro-Dur[®]
(nitroglycerin)
Transdermal Infusion System



Each unit contains 120 mg of nitroglycerin in acrylic-based polymer adhesives with a resinous cross-linking agent.

Rated release *in vivo* 0.6 mg/hr.

Caution: Federal law prohibits dispensing without prescription.

Key Pharmaceuticals, Inc.
Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

0.6 mg/hr (30 cm²)

NO VARNISH

Labeling: #FD-110
NDA No: 20-145 R0132395
Reviewed by: [Signature]
5/23/95

NOTE:
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Patient: See instructions on back panel.

Key Pharmaceuticals, Inc.
Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

DIE3633

NO VARNISH

NDC 0000-0000-00
Contents: 30 units

Nitro-Dur[®]

(nitroglycerin)
Transdermal Infusion System



Each unit contains 160 mg of nitroglycerin in acrylic-based polymer adhesives with a resinous cross-linking agent.

Rated release *in vivo* 0.8 mg/hr.

Caution: Federal law prohibits dispensing without prescription.

Key Pharmaceuticals, Inc.
Kenilworth, NJ 07033 USA
World leader in drug delivery systems.

0.8
mg/hr
(40 cm²)

Usual Dosage: Each 24 hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval, unless otherwise directed by your physician.

See top panel for lot number and expiration date.

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Directions for Use:

1. Hold unit with brown lines facing you, in an up and down position.
2. Bend sides of unit away from you, then toward you until clear plastic backing "snaps" down middle.
3. Peel off one half of plastic backing.
4. Using the other half of plastic backing as a "handle", apply sticky side of the patch to upper arm or chest. Smooth down.
5. Fold back remaining side of the patch.
6. Grasp edge of plastic "handle" by stripe and pull it across the skin.

Usual Dosage: Each 24-hour period should include a patch-on period of 12 to 14 hours, followed by a patch-free interval; unless otherwise directed by your physician.

See bottom panel for prescribing information.

Place Pharmacy Label Here:

0.8 mg/hr (40 cm²)

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Store at controlled room temperature 15°-30°C (59°-86°F).
Do not refrigerate.

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DIE3633

NO VARNISH

APR 12 1995

Labeling: #112-110
NDA No: 20-145
Rev'd: 3-13-95
Reviewed by: *[Signature]*
3/30/95