

Bayer HealthCare
Consumer Care Division



1518 '03 APR -2 19:19

April 1, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**RE: FDA, Mercury Compounds in Drugs and Food;
02/03/2003 Request for Information:
Docket No. 98N-1109**

Dear Sir or Madam:

Pursuant to the Food and Drug Administration's February 3, 2003 Request for Information, pertaining to intentionally introduced mercury compounds, Bayer HealthCare, Consumer Care Division is providing information listed below for reformulated Bayer products originally listed March 12, 1999 to Docket No. 98N-1109 for containing mercury compounds. Bayer has reformulated all Neo-Synephrine and NaSal products to no longer contain mercury.

Bayer HealthCare LLC
Consumer Care Division
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

Phone: 973 254-5000

Commercial Name	Product Code	Reformulated Drug Product – Drug Listing Date
NaSal Saline Moisturizer Spray (non-medicated)	---	Not required
NaSal Saline Moisturizer Drops (non-medicated)	---	Not required
Neo-Synephrine Mild Formula Nasal Decongestant Spray	0940	7/26/02
Neo-Synephrine Regular Strength Nasal Decongestant Spray	0950	7/26/02
Neo-Synephrine Regular Strength Nasal Decongestant Drops	0920	8/23/02
Neo-Synephrine Extra Strength Nasal Decongestant Spray	0960	7/26/02
Neo-Synephrine Extra Strength Nasal Decongestant Drops	0930	7/12/02
Neo-Synephrine 12-Hour Nasal Decongestant Spray	0970	8/23/02
Neo-Synephrine 12-Hour Extra Moisturizing Nasal Decongestant Spray	0990	8/23/02

Copies of each of the products' labeling are attached.

98N-1109

LST 4

Please contact me at 973-408-8045 or ToniAnn Dudor, Associate Director, Regulatory Affairs at 973-254-4778 should you have any questions concerning this submission.

Sincerely,
Bayer HealthCare LLC, Consumer Care Division

A handwritten signature in black ink, appearing to read "Annette C. Owens", with a long horizontal flourish extending to the right.

Annette C. Owens
Manager, Regulatory Affairs

cc: Gerald M. Rachanow
Center for Drug Evaluation and Research (HFD-560)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857



FROM THE MAKERS OF
Neo-Synephrine®
NāSal™
Saline Moisturizer

- Gently moisturizes dry, irritated nasal passages
- Non-medicated, use as often as needed
- Natural saline formulation, gentle enough for infants
- Contains no alcohol, won't sting or burn
- Fine mist spray dispenser

NāSal Saline Moisturizer provides gentle relief for dry, irritated nasal passages due to colds, low humidity, air travel, allergies, minor nose bleeds, overuse of decongestant sprays/drops and other nasal irritations. As an ideal moisturizer, it can be used with cold, allergy and sinus medications.

Also available in easy-to-use monodrops.

DIRECTIONS: For infants, children, and adults: 2 sprays in each nostril as often as needed or as directed by a doctor.

Store at room temperature. Keep this and all drugs out of the reach of children.

The use of this dispenser by more than one person may spread infection.



3 0024 1 31630 5



FROM THE MAKERS OF
Neo-Synephrine®
NāSal™
Saline Moisturizer

Contains:
water, sodium chloride,
disodium phosphate, EDTA,
sodium benzoate, benzalkonium
chloride

CONTAINS NO ALCOHOL

8696732

**NON-MEDICATED
SPRAY**

NāSal™
Saline Moisturizer
NON-MEDICATED SPRAY

USE ONLY IF NECKBAND PRINTED
WITH "Bayer" IS INTACT

FROM THE MAKERS OF
Neo-Synephrine®
NāSal™
Saline Moisturizer

**Saline
Moisturizer**
GENTLY MOISTURIZES
DRY, IRRITATED
NASAL PASSAGES

**NON-MEDICATED
SPRAY**

EASIER TO USE & DISPENSE

USE AS OFTEN
AS NEEDED

1 FL OZ (30 ml)

EXPIRES:

FROM THE MAKERS OF
Neo-Synephrine®
NāSal™
Saline Moisturizer

SATISFACTION GUARANTEED
If you are not completely
satisfied with this product,
return the unused portion of
the product and cash register
receipt to the address below
for a full refund.

**NON-MEDICATED
SPRAY**

Questions? Comments?
Please call 1-800-331-4536
Visit our website at
www.bayercare.com

Bayer

Bayer Corporation
Consumer Care Division
Mannheim, NJ 07960 USA

Product Name:	NaSal Non-Medicated Spray
Labeler Code:	N/A
Product Code:	N/A



NāSal™ Saline Moisturizer

- Natural saline formulation, gentle enough for infants.
- Contains no alcohol, won't sting or burn.
- Non-medicated, use as often as needed
- Easy-to-use monodropper.

NāSal Saline Moisturizer provides gentle relief for dry, irritated nasal passages due to colds, low humidity, air travel, allergies, minor nose bleeds, crusting, overuse of decongestant sprays/drops and other nasal irritations. As an ideal moisturizer, it can be used with cold, allergy, and sinus medications.

Also available in fine mist spray dispenser.

DIRECTIONS: For infants, children and adults, 2 to 6 drops in each nostril as often as needed or as directed by a doctor

Store at room temperature
Keep this and all drugs out of the reach of children

The use of this dispenser by more than one person may spread infection



7060



NāSal™ Saline Moisturizer NON-MEDICATED DROPS

USE ONLY IF NECKBAND
PRINTED WITH "Bayer"
IS INTACT

FROM THE MAKERS OF
Neo-Synephrine®
NāSal™
Saline Moisturizer

NāSal™ Saline Moisturizer

FOR DRY NASAL
PASSAGES
RECOMMENDED
FOR INFANTS

Contains:
water, sodium chloride,
disodium phosphate,
sodium phosphate, EDTA,
disodium benzalkonium
chloride

CONTAINS NO ALCOHOL

NON-MEDICATED
DROPS

8590144

USE AS OFTEN
AS NEEDED

1/2 FL OZ (15 ml)

EXPIRES

FROM THE MAKERS OF
Neo-Synephrine®
NāSal™
Saline Moisturizer

SATISFACTION GUARANTEED
If you are not completely
satisfied with this product,
return the unused portion of
the product and cash register
receipt to the address below
for a full refund.

NON-MEDICATED
DROPS

Bayer

Bayer Corporation
Consumer Care Division
Millsboro, PA 01906 USA

	NaSal Non-Medicated Drops	
Product Name:	NaSal Non-Medicated Drops	
Labeler Code:	N/A	
Product Code:	N/A	

Neo-Synephrine Mild Formula Spray

0280-0940-



Drug Facts

Active ingredient Purpose
Phenylephrine hydrochloride 0.25%... Nasal decongestant

Uses

- temporarily relieves nasal congestion.
- due to common cold
- due to hay fever or other respiratory allergies (allergic rhinitis)
- associated with sinusitis
- temporarily relieves stuffy nose
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose
- helps decongest sinus openings and passages;
- temporarily relieves sinus congestion and pressure

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

- do not exceed recommended dosage
- do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen
- temporary discomfort may occur such as burning, stinging, sneezing and increase in nasal discharge
- use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms persist for more than 3 days.

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions - use only as directed

to spray, squeeze bottle quickly and firmly

adults and children 6 to under 12 years (with adult supervision)	2 or 3 sprays in each nostril not more often than every 4 hours.
children under 6 years	ask a doctor

Neo-Synephrine[®]
NASAL DECONGESTANT

Drug Facts (continued)

Other Information

- store at room temperature
- protect from light

Inactive Ingredients
benzalkonium chloride, citric acid, sodium chloride, sodium citrate, water

Questions or comments?
1-800-331-4536 or
www.bayercare.com

Neo-Synephrine[®]
NASAL DECONGESTANT
MILD FORMULA SPRAY

USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT

Neo-Synephrine[®]
PHENYLEPHRINE HCl 0.25%

FAST RELIEF GOES RIGHT TO THE CORE OF YOUR CONGESTION

MILD FORMULA SPRAY

EASIER TO USE & DISPOSE

NASAL DECONGESTANT 1/2 FL OZ (15ml)

Neo-Synephrine[®]
NASAL DECONGESTANT

Bayer
Bayer Corporation
Consumer Care Division
Morristown, NJ 07960 USA

MILD FORMULA SPRAY



USE ONLY IF NECKBAND WITH "Bayer" IS INTACT

Neo-Synephrine[®]
PHENYLEPHRINE HCl 0.25%

FAST RELIEF GOES RIGHT TO THE CORE OF YOUR CONGESTION

MILD FORMULA SPRAY

NASAL DECONGESTANT
1/2 FL OZ (15ml)

151389

See Carton For Complete Information. Active Ingredient Phenylephrine hydrochloride 0.25% (use temporarily relieves) nasal congestion due to the common cold, hay fever or other respiratory allergies (allergic rhinitis) or associated with sinusitis. Temporarily relieves stuffy nose and helps clear nasal passages. Temporarily restores freer breathing and relieves sinus congestion and pressure. Warnings: Do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. See Carton For Full Warnings. Directions: to spray, squeeze bottle quickly and firmly. Adults and children 6 to under 12 years (with adult supervision): 2 or 3 sprays in each nostril not more often than every 4 hours. Children under 6 years, ask a doctor. Other Information: store at room temperature; protect from light. Bayer Corporation, Morristown, NJ 07960 USA EXP-

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1001

Drug Facts

Active ingredient Phenylephrine hydrochloride 0.5% **Purpose** Nasal decongestant

Uses

- temporarily relieves nasal congestion
 - due to common cold
 - due to hay fever or other respiratory allergies (allergic rhinitis)
 - associated with sinusitis
- temporarily relieves stuffy nose
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose
- helps decongest sinus openings and passages;
- temporarily relieves sinus congestion and pressure

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

- do not exceed recommended dosage
- do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort may occur such as burning, stinging, sneezing and increase in nasal discharge
- use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms persist for more than 3 days.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • use only as directed

- to spray, squeeze bottle quickly and firmly

adults and children 12 years and older	2 or 3 sprays in each nostril not more often than every 4 hours
children under 12 years	ask a doctor

38851

Neo-Synephrine[®] NASAL DECONGESTANT

Drug Facts (continued)

Other information

- store at room temperature
- protect from light

Inactive ingredients

benzalkonium chloride, citric acid, sodium chloride, sodium citrate, water

Questions or comments?

1-800-331-4538 or www.bayercare.com

8696929

Neo-Synephrine[®] NASAL DECONGESTANT REGULAR STRENGTH SPRAY

USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT

Neo-Synephrine[®] PHENYLEPHRINE HCl 0.5%

FAST RELIEF GOES RIGHT TO THE CORE OF YOUR CONGESTION



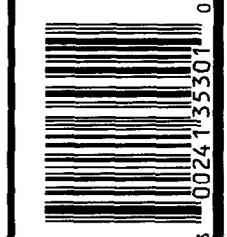
NASAL DECONGESTANT 1/2 FL OZ (15 ml)

EXPIRES:

Neo-Synephrine[®] NASAL DECONGESTANT

Bayer Corporation Consumer Care Division Morristown, NJ 07960 USA

REGULAR STRENGTH SPRAY



Neo-Synephrine Regular Strength Spray



1001

USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT

Neo-Synephrine[®] PHENYLEPHRINE HCl 0.5%

FAST RELIEF GOES RIGHT TO THE CORE OF YOUR CONGESTION

REGULAR STRENGTH SPRAY

NASAL DECONGESTANT 1/2 FL OZ (15 ml)

151362

See Carton For Complete Information. Active ingredient Phenylephrine hydrochloride 0.5% (5mg) temporarily relieves nasal congestion due to the common cold, hay fever or other respiratory allergies (allergic rhinitis) or associated with sinusitis. Temporarily relieves stuffy nose and helps clear nasal passages. Temporarily restores freer breathing and relieves sinus congestion and pressure. **Warnings:** Do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen. If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. See Carton for Full Warnings. **Directions:** to spray, squeeze bottle quickly and firmly. Adults and children 12 years and older, 2 or 3 sprays in each nostril not more often than every 4 hours. Children under 12 years, ask a doctor. Other information: store at room temperature, protect from light. Bayer Corporation, Morristown, NJ 07960 USA EXP:

8696937

02-80-0950-



Drug Facts

Active Ingredient
Phenylephrine hydrochloride 0.5%.....**Purpose**
.....Nasal decongestant

Uses

- temporarily relieves nasal congestion:
 - due to common cold
 - due to hay fever or other respiratory allergies (allergic rhinitis)
 - associated with sinusitis
- temporarily relieves stuffy nose
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose
- helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure

Warnings

Ask a doctor before use if you have

- heart disease • high blood pressure • thyroid disease • diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

- do not exceed recommended dosage
- do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort may occur such as burning, stinging, sneezing and increase in nasal discharge
- use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms persist for more than 3 days.

3 0024 1 35105 4



Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Use only as directed

adults and children 12 years and older	2 or 3 drops in each nostril not more often than every 4 hours
children under 12 years	ask a doctor

Other information

- store at room temperature
- protect from light

Inactive ingredients
benzalkonium chloride, citric acid, sodium chloride, sodium citrate, water.

Questions or comments?
1-800-331-4636 or www.bayercare.com

8695833

Neo-Synephrine[®]
NASAL DECONGESTANT
REGULAR STRENGTH DROPS

DO NOT USE IF IMPRINTED BOTTLE OVERWRAP IS BROKEN OR MISSING

Neo-Synephrine[®]
PHENYLEPHRINE HCl 0.5%
FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION

REGULAR STRENGTH DROPS

EVERY TO USE & DISPENSE

NASAL DECONGESTANT 1/2 FL OZ (15ml)

Neo-Synephrine[®]
NASAL

REGULAR STRENGTH DROPS

Bayer

Bayer Corporation
One Parker Center Drive
Baltimore, MD 21286 USA

Neo-Synephrine Regular Strength Drops		
Product Name:	0280	0920
Labeler Code:		
Product Code:		

EXPIRES:

DO NOT USE IF IMPRINTED BOTTLE OVERWRAP IS BROKEN OR MISSING

8695841

Bayer
Bayer Corporation
Consumer Care Division
Horsholm, NJ 07991 USA

Neo-Synephrine[®]
PHENYLEPHRINE HCl 0.5%
FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION

REGULAR STRENGTH DROPS

NASAL DECONGESTANT 1/2 FL OZ (15ml)

See Container for Complete Medication Information. Active Ingredient: Phenylephrine HCl 0.5%. Temporary relief of nasal congestion due to common cold, hay fever or other respiratory allergies (allergic rhinitis) or associated with sinusitis. Temporarily relieves stuffy nose and helps clear nasal passages and shrinks swollen membranes. Temporarily restores freer breathing through the nose. Temporarily relieves sinus congestion and pressure. **WARNING:** Ask a doctor before use if you have heart disease, high blood pressure, thyroid disease, diabetes or difficulty in urination due to enlargement of the prostate gland. Frequent or prolonged use may cause nasal congestion to recur or worsen. Temporary discomfort may occur such as burning, stinging, sneezing and increase in nasal discharge. Use of this container by more than one person may spread infection. **Directions:** Use only as directed. **Other information:** Store at room temperature, protect from light. **Inactive ingredients:** benzalkonium chloride, citric acid, sodium chloride, sodium citrate, water. **Questions or comments?** 1-800-331-4636 or www.bayercare.com

Neo-Synephrine Extra Strength Spray 0280-0960-



Drug Facts

Active Ingredient Purpose
Phenylephrine hydrochloride 1.0%.....Nasal decongestant

Uses

- temporarily relieves nasal congestion
 - due to common cold
 - due to hay fever or other respiratory allergies (allergic rhinitis)
 - associated with sinusitis
- temporarily relieves stuffy nose
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose
- helps decongest sinus openings and passages;
- temporarily relieves sinus congestion and pressure

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

- do not exceed recommended dosage
- do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen
- temporary discomfort may occur such as burning, stinging, sneezing and increase in nasal discharge
- use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms persist for more than 3 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Neo-Synephrine
NASAL DECONGESTANT

Drug Facts (continued)

Directions

- use only as directed
- to spray, squeeze bottle quickly and firmly

adults and children 12 years and older	2 or 3 sprays in each nostril not more often than every 4 hours.
children under 12 years	ask a doctor

Other information

- store at room temperature
- protect from light

Inactive ingredients
benzalkonium chloride, citric acid, sodium chloride, sodium citrate, water

Questions or comments?
1-800-331-4536 or www.bayercare.com

Neo-Synephrine
NASAL DECONGESTANT
EXTRA STRENGTH SPRAY

USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT

Neo-Synephrine
PHENYLEPHRINE HCl 1.0%

FAST RELIEF GOES RIGHT TO THE CORE OF YOUR CONGESTION

EXTRA STRENGTH SPRAY

EASIER TO USE & DISPENSE

NASAL DECONGESTANT 1/2 FL OZ (15ml)

Neo-Synephrine
NASAL DECONGESTANT

Bayer

Bayer Corporation
Consumer Care Division
Morristown, NJ 07960 USA

EXTRA STRENGTH SPRAY

0024135202 0

8696945

EXPIRES:



USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT

Neo-Synephrine
PHENYLEPHRINE HCl 1.0%

FAST RELIEF GOES RIGHT TO THE CORE OF YOUR CONGESTION

EXTRA STRENGTH SPRAY

NASAL DECONGESTANT
1/2 FL OZ (15ml)

151346

See Carton For Complete Information. Active Ingredient: Phenylephrine hydrochloride 1.0%. Uses: temporarily relieves nasal congestion due to the common cold, hay fever or other respiratory allergies (allergic rhinitis) or associated with sinusitis. temporarily relieves stuffy nose and helps clear nasal passages. temporarily restores freer breathing and relieves sinus congestion and pressure. **Warnings:** Do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. See Carton For Full Warnings, Directions to spray, squeeze bottle quickly and firmly. Adults and children 12 years and older: 2 or 3 sprays in each nostril not more often than every 4 hours. Children under 12 years, ask a doctor. **Other information:** store at room temperature; protect from light. Bayer Corporation, Morristown, NJ 07960 USA
EXP:

8696953



Drug Facts

Active Ingredient
Phenylephrine hydrochloride 1.0%.....**Purpose**
Nasal decongestant

Uses

- temporarily relieves nasal congestion:
 - due to common cold
 - due to hay fever or other respiratory allergies (allergic rhinitis)
 - associated with sinusitis
- temporarily relieves stuffy nose
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose
- helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure

Warnings

Ask a doctor before use if you have

- heart disease • high blood pressure • thyroid disease • diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

- do not exceed recommended dosage
- do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort may occur such as burning, stinging, sneezing and increase in nasal discharge
- use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms persist for more than 3 days.



Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

use only as directed

adults and children 12 years and older	2 or 3 drops in each nostril not more often than every 4 hours
children under 12 years	ask a doctor

Other Information

- store at room temperature
- protect from light

Inactive Ingredients
benzalkonium chloride, citric acid, sodium chloride, sodium citrate, water

Questions or comments?
1-800-331-4536 or www.bayercare.com

Neo-Synephrine®
NASAL DECONGESTANT
EXTRA STRENGTH DROPS

DO NOT USE IF IMPRINTED BOTTLE OVERWRAP IS BROKEN OR MISSING

Neo-Synephrine®
PHENYLEPHRINE HCl 1.0%
FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION

EXTRA STRENGTH DROPS

NASAL DECONGESTANT 1/2 FL OZ (15 ml)

Neo-Synephrine®
NASAL DECONGESTANT

EXTRA STRENGTH DROPS

Bayer

Bayer Corporation
Consumer Care Division
Mannheim, NJ 07960 USA

EXPIRES:

DO NOT USE IF IMPRINTED BOTTLE OVERWRAP IS BROKEN OR MISSING

8695825

Bayer
Consumer Care Division
Mannheim, NJ 07960 USA

Neo-Synephrine®
PHENYLEPHRINE HCl 1.0%
FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION

EXTRA STRENGTH DROPS

NASAL DECONGESTANT 1/2 FL OZ (15 ml)

See Back for Complete Information. Active Ingredient: Phenylephrine hydrochloride 1.0%. Inactive Ingredients: benzalkonium chloride, citric acid, sodium chloride, sodium citrate, water. **Uses:** temporarily relieves nasal congestion associated with sinusitis; temporarily relieves stuffy nose and helps clear nasal passages and drains swollen membranes. Temporarily restores freer breathing. Temporarily relieves sinus congestion and pressure. **Warnings:** Ask a doctor before use if you have heart disease, high blood pressure, thyroid disease, difficulty in urination due to enlargement of the prostate gland, when taking other drugs, or if you are pregnant or breast-feeding. **Directions:** Adults and children 12 years and older: 2 or 3 drops in each nostril not more often than every 4 hours. Children under 12 years: ask a doctor. **Other Information:** Store at room temperature. Protect from light. **Questions or comments?** 1-800-331-4536 or www.bayercare.com

Neo-Synephrine Extra Strength Drops 0280-0930



0907

Drug Facts

Active Ingredient Purpose
Oxymetazoline hydrochloride 0.05%.....Nasal decongestant

Uses
temporarily relieves nasal congestion.
• due to common cold
• due to hay fever or other respiratory allergies
• associated with sinusitis
temporarily relieves stuffy nose.
• helps clear nasal passages, shrinks swollen membranes.
• temporarily restores freer breathing through the nose
• helps decongest sinus openings and passages;
temporarily relieves sinus congestion and pressure.

Warnings
Do not exceed recommended dosage.
Ask a doctor before use if you have
• heart disease • high blood pressure • thyroid disease
• diabetes
• difficulty in urination due to enlargement of the prostate gland

When using this product
• temporary discomfort such as burning, stinging, sneezing, and increase in nasal discharge may occur
• use by more than one person may spread infection
Stop use and ask a doctor if symptoms persist for more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen.

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
• use only as directed
• to spray, squeeze bottle quickly and firmly
adults and children 6 to 12 years (with adult supervision) 2 to 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in 24 hours.

Neo-Synephrine
NASAL DECONGESTANT

Drug Facts (continued)
children under 6 years ask a doctor.

Other information
• store at room temperature.
• protect from light.

Inactive ingredients
benzalkonium chloride, disodium phosphate, EDTA disodium, sodium chloride, sodium phosphate, water

Questions or comments?
1-800-331-4536 or
www.bayercare.com

8590098

Neo-Synephrine
NASAL DECONGESTANT
12 HOUR SPRAY

USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT

Neo-Synephrine
NASAL DECONGESTANT
OXYMETAZOLINE HCl 0.05%

FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION

12 HOUR SPRAY



NASAL DECONGESTANT 1/2 FL OZ (15ml)

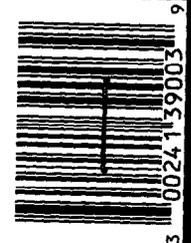
EXPIRES:

Neo-Synephrine
NASAL DECONGESTANT



Bayer Corporation
Consumer Care Division
Morristown, NJ 07960 USA

12 HOUR SPRAY



Product Name:	Neo-Synephrine 12 Hour Spray
Labeler Code:	0280
Product Code:	0970

2060



USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT

Neo-Synephrine
OXYMETAZOLINE HCl 0.05%
FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION
12 HOUR SPRAY
NASAL DECONGESTANT
1/2 FL OZ (15ml)

151400

See Carton For Complete Information. Active ingredient Oxymetazoline HCl 0.05% (nasal) temporarily relieves nasal congestion associated with the common cold and hay fever or temporarily relieves stuffy nose and restores free breathing through the nose. Helps clear nasal passages; shrinks swollen membranes. Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure. **Do not exceed recommended dosage.** If pregnant or breast-feeding, ask a health professional before use. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away. **Directions:** use only as directed, to spray, squeeze bottle quickly and firmly. Adults and children 6 to under 12 years (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in 24 hours. Children under 6 years - Ask a doctor. Other medicines, store all over temperature, protect from light. Bayer Corporation, Morristown, NJ 07960 USA
EXP:

151419



0892

Drug Facts

Active Ingredient Purpose
Oxymetazoline hydrochloride 0.05%...Nasal decongestant

Uses

- temporarily relieves nasal congestion:
- due to common cold
- due to hay fever or other respiratory allergies
- associated with sinusitis
- temporarily relieves stuffy nose.
- helps clear nasal passages; shrinks swollen membranes.
- temporarily restores freer breathing through the nose.
- helps decongest sinus openings and passages;
- temporarily relieves sinus congestion and pressure.

Warnings

- Do not exceed recommended dosage.
- Ask a doctor before use if you have
- heart disease • high blood pressure • thyroid disease
 - diabetes
 - difficulty in urination due to enlargement of the prostate gland

When using this product

- temporary discomfort such as burning, stinging, sneezing, and increase in nasal discharge may occur
- use by more than one person may spread infection

Stop use and ask a doctor if symptoms persist for more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen.

If you are pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- use only as directed
 - to spray, squeeze bottle quickly and firmly
- adults and children 6 to under 12 years (with adult supervision) 2 to 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in 24 hours.

Neo-Synephrine
NASAL DECONGESTANT

Drug Facts (continued)

children under 6 years ask a doctor.

Other Information

- store at room temperature.
- protect from light.

Inactive Ingredients

benzalkonium chloride, disodium phosphate, EDTA disodium, glycerin, sodium chloride, sodium phosphate, water

Questions or comments?

1-800-331-4536 or www.bayercare.com

8590020



2680

USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT.



151427

Neo-Synephrine
NASAL DECONGESTANT
EXTRA MOISTURIZING 12 HOUR SPRAY

USE ONLY IF NECKBAND PRINTED WITH "Bayer" IS INTACT

Neo-Synephrine
NASAL DECONGESTANT
OXYMETAZOLINE HCl 0.05%

FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION

EXTRA MOISTURIZING
12 HOUR SPRAY
EASIER TO USE & DISPENSE

NASAL DECONGESTANT 1/2 FL OZ (15ml)

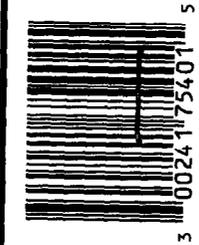
EXPIRES:

Neo-Synephrine
NASAL DECONGESTANT



Bayer Corporation
Consumer Care Division
Morristown, NJ 07960 USA

EXTRA MOISTURIZING
12 HOUR SPRAY



151435

See Carton For Complete Information. Active ingredient: Oxymetazoline HCl 0.05%. Use: temporarily relieves nasal congestion associated with sinusitis, the common cold, and hay fever or other respiratory allergies (allergic rhinitis). temporarily relieves stuffy nose and restores freer breathing through the nose. Helps clear nasal passages; shrinks swollen membranes. Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure. Warnings: Do not exceed recommended dosage. If pregnant or breast-feeding, ask a health professional before use. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Directions: use only as directed. To spray, squeeze bottle quickly and firmly. adults and children 6 to under 12 years (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. do not exceed 2 doses in 24 hours. children under 6 years - ask a doctor. Other information: store at room temperature, protect from light. Bayer Corporation, Morristown, NJ 07960 USA. EXP:

Product Name:	Neo-Synephrine Extra Moisturizing 12 Hour Spray
Labeler Code:	0280
Product Code:	0990