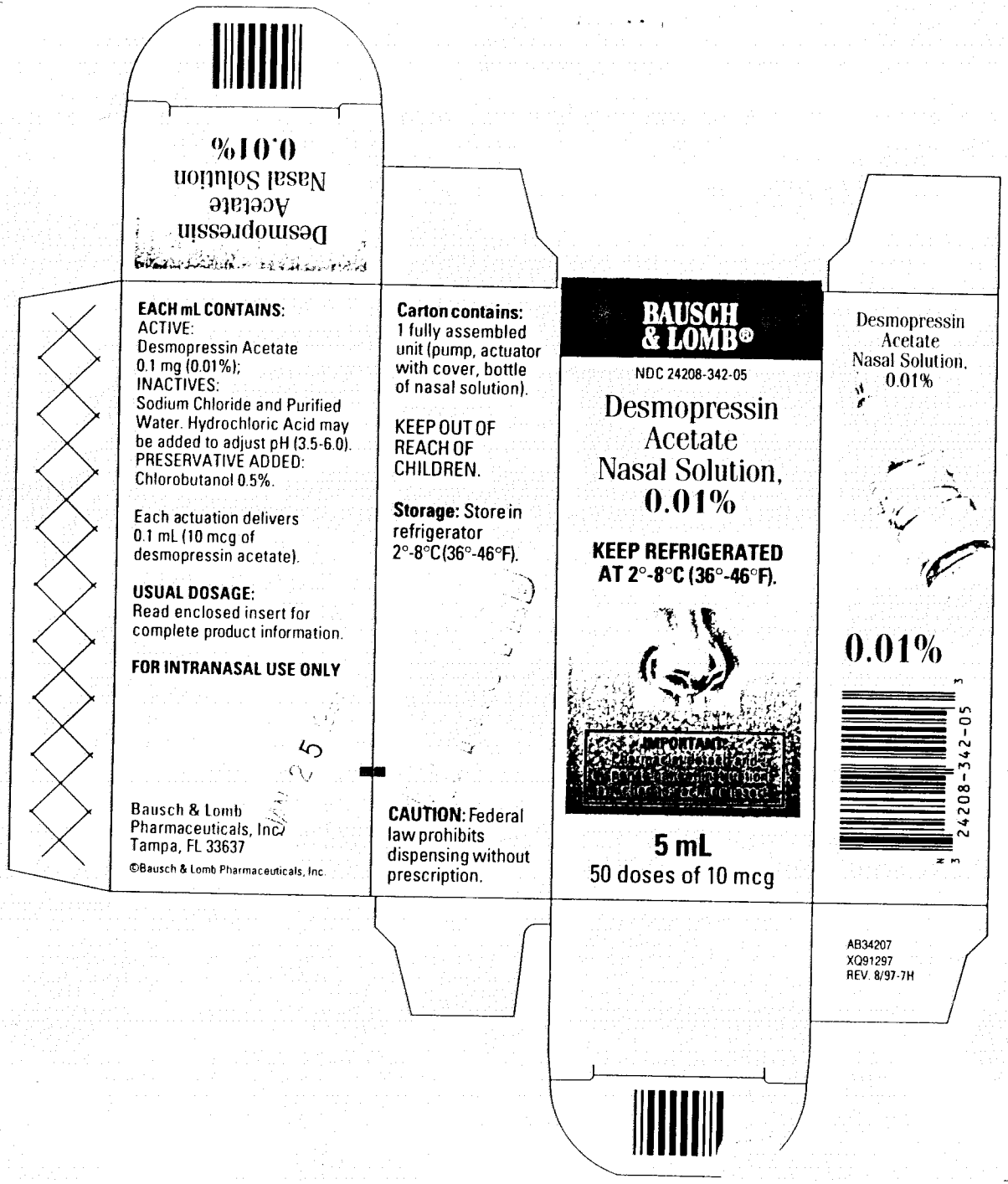
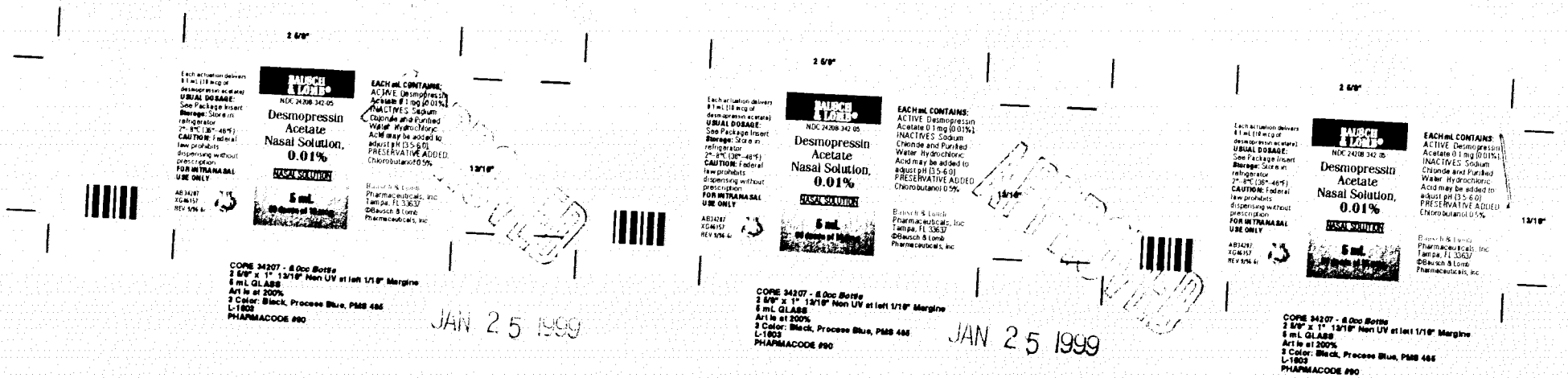
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 74-830

PRINTED LABELING



CORE 34207 / 5mL CARTON
Art is at 100%
Box Dimensions: 1 5/8" x 1 1/8" x 3 13/16"
3 Color: Black, Process Blue & PMS 485
PHARMACODE #
L-2042
SCANNER BAR LOCATION: 0.75" (12)


2 5/8"
Each actuation delivers 0.1 mL (10 mcg of desmopressin acetate)
USUAL DOSAGE: See Package Insert
Storage: Store in refrigerator 2°-8°C (36°-46°F)
CAUTION: Federal law prohibits dispensing without prescription
FOR INTRANASAL USE ONLY
AB34287
XG46157
REV 5/96 6
BAUSCH & LOMB
NDC 24208-342-05
Desmopressin Acetate Nasal Solution, 0.01%
NASAL SOLUTION
5 mL
EACH mL CONTAINS:
ACTIVE: Desmopressin Acetate 0.1 mg (0.01%)
INACTIVES: Sodium Chloride and Purified Water. Hydrochloric Acid may be added to adjust pH (3.5-6.0).
PRESERVATIVE ADDED: Chlorobutanol 0.5%
Bausch & Lomb Pharmaceuticals, Inc Tampa, FL 33637
©Bausch & Lomb Pharmaceuticals, Inc
13/16"
CORE 34207 - 6.0cc Bottle
2 5/8" x 1" 13/16" Non UV at left 1/16" Margine
6 mL GLASS
Art is at 200%
3 Color: Black, Process Blue, PMS 485
L-1803
PHARMACODE #90
JAN 25 1999

BAUSCH & LOMB®

PHARMACIST — DETACH INSTRUCTIONS FOR PATIENT

Desmopressin Acetate Nasal Solution, 0.01%

FOR INTRANASAL USE ONLY

DESCRIPTION:
Desmopressin Acetate Nasal Solution 0.01% is a synthetic analogue of the natural pituitary hormone 8-arginine vasopressin (ADH), an antidiuretic hormone affecting renal water conservation. The structural formula for the active ingredient is:

SCH_2CH_2CO-Tyr-Phe-Gln-Asn-Cys-Pro-D-Arg-Gly-$NH_2 \cdot C_2H_4O_2 \cdot 3H_2O$

$C_{48}H_{74}N_{14}O_{17}S_2$ Mol. Wt. 1183.34

Chemical Name: 1-(3-mercaptopropionic acid)-8-D-arginine vasopressin monoacetate (salt) trihydrate.

Each mL Contains: ACTIVE: Desmopressin Acetate 0.1 mg (0.01%); INACTIVES: Sodium Chloride and Purified Water. Hydrochloric Acid may be added to adjust pH (3.5 - 6.0). PRESERVATIVE ADDED: Chlorobutanol 0.5%.

The desmopressin acetate nasal solution compression pump delivers 0.1 mL (10 mcg) of desmopressin acetate nasal solution per spray.

CLINICAL PHARMACOLOGY:
Desmopressin acetate is a synthetic analog of the natural hormone arginine vasopressin. One mL (0.1 mg) of intranasal desmopressin acetate has an antidiuretic activity of about 400 IU; 10 mcg of desmopressin acetate is equivalent to 40 IU.
1. The biphasic half-lives for desmopressin acetate were 7.8 and 75.5 minutes for the fast and slow phases, compared with 2.5 and 14.5 minutes for lysine vasopressin, another form of the hormone used in this condition. As a result, intranasal desmopressin acetate provides a prompt onset of antidiuretic action with a long duration after each administration.
2. The change in structure of arginine vasopressin to desmopressin acetate has resulted in a decreased vasopressor action and decreased actions on visceral smooth muscle relative to the enhanced antidiuretic activity, so that clinically effective antidiuretic doses are usually below threshold levels for effects on vascular or visceral smooth muscle.
3. Desmopressin acetate administered intranasally has an antidiuretic effect about one-tenth that of an equivalent dose administered by injection.

INDICATIONS AND USAGE:
Primary Nocturnal Enuresis: Desmopressin acetate nasal solution is indicated for the management of primary nocturnal enuresis. It may be used alone or adjunctive to behavioral conditioning or other non-pharmacological intervention. It has been shown to be effective in some cases that are refractory to conventional therapies.

Central Cranial Diabetes Insipidus: Desmopressin acetate nasal solution is indicated as antidiuretic replacement therapy in the management of central cranial diabetes insipidus and for management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region. It is ineffective for the treatment of nephrogenic diabetes insipidus.

The use of desmopressin acetate nasal solution in patients with an established diagnosis will result in a reduction in urinary output with increase in urine osmolality and a decrease in plasma osmolality. This will allow the resumption of a more normal life-style with a decrease in urinary frequency and nocturia.

There are reports of an occasional change in response with time, usually greater than 6 months. Some patients may show a decreased responsiveness, others a shortened duration of effect. There is no evidence this effect is due to the development of binding antibodies but may be due to a local inactivation of the peptide.

Patients are selected for therapy by establishing the diagnosis by means of the water deprivation test, the hypertonic saline infusion test, and/or the response to antidiuretic hormone. Continued response to intranasal desmopressin acetate can be monitored by urine volume and osmolality.

Desmopressin acetate nasal solution is also available as a solution for injection when the intranasal route may be compromised. These situations include nasal congestion and blockage, nasal discharge, atrophy of nasal mucosa, and severe atrophic rhinitis. Intranasal delivery may also be inappropriate where there is an impaired level of consciousness. In addition, cranial surgical procedures, such as transsphenoidal hypophysectomy create situations where an alternative route of administration is needed as in cases of nasal packing or recovery from surgery.

CONTRAINDICATION:
Desmopressin acetate nasal solution is contraindicated in individuals with known hypersensitivity to desmopressin acetate or to any of the components of desmopressin acetate nasal solution.

WARNINGS:
1. For intranasal use only.
2. In very young and elderly patients in particular, fluid intake should be adjusted downward in order to decrease the potential occurrence of water intoxication and hyponatremia. Particular attention should be paid to the possibility of the rare occurrence of an extreme decrease in plasma osmolality that may result in seizures which could lead to coma.

PRECAUTIONS:
General: Intranasal desmopressin acetate at high dosage has infrequently produced a slight elevation of blood pressure, which disappeared with a reduction in dosage. The drug should be used with caution in patients with coronary artery insufficiency and/or hypertensive cardiovascular disease because of possible rise in blood pressure.

Desmopressin acetate should be used with caution in patients with conditions associated with fluid and electrolyte imbalance, such as cystic fibrosis, because these patients are prone to hyponatremia.

Rare severe allergic reactions have been reported with desmopressin acetate. Anaphylaxis has been reported with intravenous administration of desmopressin acetate injection, but not with intranasal desmopressin acetate.

Central Cranial Diabetes Insipidus: Since intranasal desmopressin acetate is used intranasally, changes in the nasal mucosa such as scarring, edema, or other disease may cause erratic, unreliable absorption in which case intranasal desmopressin acetate should not be used. For such situations, desmopressin acetate injection should be considered.

Primary Nocturnal Enuresis: If changes in the nasal mucosa have occurred, unreliable absorption may result. Desmopressin acetate should be discontinued until the nasal problems resolve.

Laboratory Tests: Laboratory tests for following the patient with central cranial diabetes insipidus or post-surgical or head trauma-related polyuria and polydipsia include urine volume and osmolality. In some cases plasma osmolality measurements may be required. For the healthy patient with primary nocturnal enuresis, serum electrolytes should be checked at least once if therapy is continued beyond 7 days.

Drug Interactions: Although the pressor activity of intranasal desmopressin acetate is very low compared to the antidiuretic activity, use of large doses of intranasal desmopressin acetate with other pressor agents should only be done with careful patient monitoring.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with desmopressin acetate have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy-Category B: Fertility studies have not been done. Teratology studies in rats and rabbits at doses from 0.05 to 10 µg/kg/day (approximately 0.1 times the maximum systemic human exposure in rats and up to 38 times the maximum systemic human exposure in rabbits based on surface area, mg/m^2) revealed no harm to the fetus due to desmopressin acetate. There are, however no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Several publications of desmopressin acetate's use in the management of diabetes insipidus during pregnancy are available; these include a few anecdotal reports of congenital anomalies and low birth weight babies. However, no causal connection between these events and desmopressin acetate

PHARMACIST — DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

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DELIVERING DESMOPRES

Your doctor has prescri
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CAUTION: The nasal spray p
10 micrograms each. Any
should be discarded since t
actuation may be substanti
drug. Do not transfer any re
Please read the following ins
spray pump.

USING YOUR DESMOPRES

1. Remove protective cap.
2. **The spray pump must be i**
prime pump, press down
3. Once primed, the spray p
medication each time it is
accuracy, tilt bottle so thi
from the deepest portion

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PHARMACIST — DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

BAUSCH & LOMB®

PATIENT INSTRUCTIONS

Desmopressin Acetate Nasal Solution, 0.01%

– A BETTER WAY TO DELIVER DESMOPRESSIN ACETATE NASAL SOLUTION –

DELIVERING DESMOPRESSIN ACETATE MORE EFFICIENTLY

Your doctor has prescribed desmopressin acetate nasal solution as antidiuretic hormone replacement therapy. Follow the dosage schedule that is specified. The convenient nasal spray pump provides an efficient, reliable way to administer your medication. It is important, however, to adhere completely to the following instructions so that you will always receive a consistent dose of your medication.

CAUTION: The nasal spray pump accurately delivers 50 doses of 10 micrograms each. Any solution remaining after 50 doses should be discarded since the amount delivered thereafter per actuation may be substantially less than 10 micrograms of the drug. Do not transfer any remaining solution to another bottle. Please read the following instructions carefully before using the spray pump.

USING YOUR DESMOPRESSIN ACETATE NASAL SPRAY PUMP

1. Remove protective cap.
2. **The spray pump must be primed prior to the first use. To prime pump, press down five (5) times.**
3. Once primed, the spray pump delivers 10 micrograms of medication each time it is pressed. To ensure dosing accuracy, tilt bottle so that dip tube inside the bottle draws from the deepest portion of the medication.

has been established. A 15-year, Swedish epidemiologic study of the use of desmopressin acetate in pregnant women with diabetes insipidus found the rate of birth defects to be no greater than that in the general population; however, the statistical power of this study is low. As opposed to preparations containing natural hormones, desmopressin acetate in antidiuretic doses has no uterotonic action and the physician will have to weigh the therapeutic advantages against the possible risks in each case.

Nursing Mothers: There have been no controlled studies in nursing mothers. A single study in a postpartum woman demonstrated a marked change in plasma, but little if any change in assayable desmopressin acetate in breast milk following an intranasal dose of 10 mcg. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when desmopressin acetate is administered to a nursing woman.

Pediatric Use:
Primary Nocturnal Enuresis: Desmopressin acetate has been used in childhood nocturnal enuresis. Short-term (4-8 weeks) desmopressin acetate administration has been shown to be safe and modestly effective in pediatric patients aged 6 years or older with severe childhood nocturnal enuresis. Adequately controlled studies with intranasal desmopressin acetate in primary nocturnal enuresis have not been conducted beyond 4-8 weeks. The dose should be individually adjusted to achieve the best results.

Central Cranial Diabetes Insipidus: Desmopressin acetate has been used in pediatric patients with diabetes insipidus. Use in pediatric patients will require careful fluid intake restriction to prevent possible hyponatremia and water intoxication. The dose must be individually adjusted to the patient with attention in the very young to the danger of an extreme decrease in plasma osmolality with resulting convulsions. Dose should start at 0.05 mL or less.

Since the spray cannot deliver less than 0.1 mL (10 mcg), smaller doses should be administered using the rhinal tube delivery system. Do not use the nasal spray in pediatric patients requiring less than 0.1 mL (10 mcg) per dose.

There are reports of an occasional change in response with time, usually greater than 6 months. Some patients may show a decreased responsiveness, others a shortened duration of effect. There is no evidence this effect is due to the development of binding antibodies but may be due to a local inactivation of the peptide.

ADVERSE REACTIONS:
Infrequently, high dosages of intranasal desmopressin acetate have produced transient headache and nausea. Nasal congestion, rhinitis and flushing have also been reported occasionally along with mild abdominal cramps. These symptoms disappeared with reduction in dosage. Nosebleed, sore throat, cough and upper respiratory infections have also been reported.

The following table lists the percentage of patients having adverse experiences without regard to relationship to study drug from the pooled pivotal study data for nocturnal enuresis.

	PLACEBO	Desmopressin Acetate	
ADVERSE REACTION	(N=59)	20 mcg (N=60)	40 mcg (N=61)
BODY AS A WHOLE	%	%	%
Abdominal Pain	0	2	2
Asthenia	0	0	2
Chills	0	0	2
Headache	0	2	5
Throat Pain	2	0	0
NERVOUS SYSTEM			
Depression	2	0	0
Dizziness	0	0	3
RESPIRATORY SYSTEM			
Epistaxis	2	3	0
Nostril Pain	0	2	0
Respiratory Infection	2	0	0
Rhinitis	2	8	3
CARDIOVASCULAR SYSTEM			
Vasodilation	2	0	0
DIGESTIVE SYSTEM			
Gastrointestinal Disorder	0	2	0
Nausea	0	0	2
SKIN & APPENDAGES			
Leg Rash	2	0	0
Rash	2	0	0
SPECIAL SENSES			
Conjunctivitis	0	2	0
Edema Eyes	0	2	0
Lachrymation Disorder	0	0	2

See **WARNINGS** for the possibility of water intoxication and hyponatremia.

OVERDOSAGE:
See ADVERSE REACTIONS above. In case of overdosage, the dose should be reduced, frequency of administration decreased, or the drug withdrawn according to the severity of the condition. There is no known specific antidote for desmopressin acetate or desmopressin acetate nasal solution.

An oral LD_{50} has not been established. An intravenous dose of 2 mg/ kg in mice demonstrated no effect.

DOSAGE AND ADMINISTRATION:
Primary Nocturnal Enuresis: Dosage should be adjusted according to the individual. The recommended initial dose for those 6 years of age and older is 20 mcg or 0.2 mL solution intranasally at bedtime. Adjustment up to 40 mcg is suggested if the patient does not respond. Some patients may respond to 10 mcg and adjustment to that lower dose may be done if the patient has shown a response to 20 mcg. It is recommended that one-half of the dose be administered per nostril. Adequately controlled studies with intranasal desmopressin acetate in primary nocturnal enuresis have not been conducted beyond 4-8 weeks.

Central Cranial Diabetes Insipidus: Desmopressin acetate dosage must be determined for each individual patient and adjusted according to the diurnal pattern of response. Response should be estimated by two parameters: adequate duration of sleep and adequate, not excessive, water turnover. Patients with nasal congestion and blockage have often responded well to intranasal desmopressin acetate. The usual dosage range in adults is 0.1 to 0.4 mL daily, as a single dose or divided into two or three doses. Most adults require 0.2 mL daily in two divided doses. The morning and evening doses should be separately adjusted for an adequate diurnal rhythm of water turnover. For children aged 3 months to 12 years, the usual dosage range is 0.05 to 0.3 mL daily, either as a single dose or divided into two doses. About 1/4 to 1/3 of patients can be controlled by a single daily dose of intranasal desmopressin acetate.

The nasal spray pump can only deliver doses of 0.1 mL (10 mcg) or multiples of 0.1 mL. If doses other than these are required, the rhinal tube delivery system may be used.

The spray pump must be primed prior to the first use. **To prime pump, press down five (5) times.** The bottle will now deliver 10 mcg of drug per spray. Discard intranasal desmopressin acetate after 50 sprays since the amount delivered thereafter per spray may be substantially less than 10 mcg of drug.

HOW SUPPLIED:
Desmopressin Acetate Nasal Solution, 0.01% is supplied in a bottle with nasal pump dispenser with dust cover and with patient instructions in the following size: 5 mL bottles - Prod. No. 34207

Storage: Store in refrigerator at 2°-8°C (36°-46°F).
When traveling, product will maintain stability for up to 3 weeks when stored at room temperature, 22°C (72°F).

KEEP OUT OF REACH OF CHILDREN.

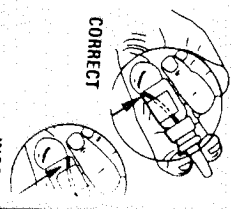
Caution: Federal law prohibits dispensing without prescription.

Bausch & Lomb
Pharmaceuticals, Inc.
Tampa, FL 33637

X050319 REV. 11/98-8K

INCOR

To administer a 10-micr
dose, place the spray no
nostril and press the spray
once. If a higher dose has
prescribed, spray half th
in each nostril. The spray
cannot be used for dose
than 10 micrograms or
other than multiples
micrograms.



4. Replace the protective
on bottle after use, and st
refrigerator. The pump will
primed for up to one week u
refrigeration. If the produc
not been used for a period o
week, re-prime the pum
pressing once.

5. We have included a con
ient check-off chart to as
you in keeping track
medication doses used. This
help assure that you receiv
"full doses" of medicati
Please note that the bottle
been filled with extra solutio
accommodate the initial prim
activity.

Asthenia			
Chills	0	0	2
Headache	0	2	5
Throat Pain	2	0	0
NERVOUS SYSTEM			
Depression	2	0	0
Dizziness	0	0	3
RESPIRATORY SYSTEM			
Epistaxis	2	3	0
Nostril Pain	0	4	0
Respiratory Infection	2	0	3
Rhinitis	2	8	3
CARDIOVASCULAR SYSTEM			
Vasodilation	2	0	0
DIGESTIVE SYSTEM			
Gastrointestinal Disorder	0	2	2
Nausea	0	0	2
SKIN & APPENDAGES			
Leg Rash	2	0	0
Rash	2	0	0
SPECIAL SENSES			
Conjunctivitis	0	2	0
Edema Eyes	0	2	0
Lachrymation Disorder	0	0	2

4

See **WARNINGS** for the possibility of water intoxication and hyponatremia.

OVERDOSAGE:
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The nasal spray pump can only deliver doses of 0.1 mL (10 mcg) or multiples of 0.1 mL. If doses other than these are required, the rhinal tube delivery system may be used.

The spray pump must be primed prior to the first use. **To prime pump, press down five (5) times.** The bottle will now deliver 10 mcg of drug per spray. Discard intranasal desmopressin acetate after 50 sprays since the amount delivered thereafter per spray may be substantially less than 10 mcg of drug.

HOW SUPPLIED:
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Storage: Store in refrigerator at 2°-8°C (36°-46°F).
When traveling, product will maintain stability for up to 3 weeks when stored at room temperature, 22°C (72°F).

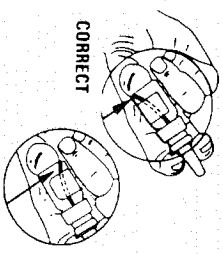
KEEP OUT OF REACH OF CHILDREN.

Caution: Federal law prohibits dispensing without prescription.

Bausch & Lomb
Pharmaceuticals, Inc.
Tampa, FL 33637

XO50319 REV. 11/98-8K

INCORRECT **CORRECT**



To administer a 10-microgram dose, place the spray nozzle in nostril and press the spray pump once. If a higher dose has been prescribed, spray half the dose in each nostril. The spray pump cannot be used for doses less than 10 micrograms or doses other than multiples of 10 micrograms.

4. Replace the protective cap on bottle after use, and store in refrigerator. The pump will stay primed for up to one week under refrigeration. If the product has not been used for a period of one week, re-prime the pump by pressing once.

5. We have included a convenient check-off chart to assist you in keeping track of medication doses used. This will help assure that you receive 50 "full doses" of medication. Please note that the bottle has been filled with extra solution to accommodate the initial priming activity.

Storage: Store in refrigerator at 2°-8°C (36°-46°F). When traveling, product will maintain stability for up to 3 weeks when stored at room temperature, 22°C (72°F.)

Bausch & Lomb
Pharmaceuticals, Inc.
Tampa, FL 33637

Desmopressin Acetate Nasal Solution
50 Dose Check-off

1	2	3	4	5
6	7	8	9	10
11	12	13	14	15
16	17	18	19	20
21	22	23	24	25
26	27	28	29	30
31	32	33	34	35
36	37	38	39	40
41	42	43	44	45
46	47	48	49	50

Retain with medication or affix in convenient location, e.g., refrigerator door.

Starting with dose #1, check off after each administration.

Discard medication after 50 doses.