

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20 - 583**

FINAL PRINTED LABELING

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA

**DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO
ENSURE ONLY CORRECT AND CURRENT INFORMATION IS
DISSEMINATED TO THE PUBLIC.**

THIS SECTION
WAS
DETERMINED
NOT
TO BE
RELEASABLE

6 pages

SHAKE VIGOROUSLY
BEFORE USING
USUAL DOSAGE:
See Package insert
Storage: Store upright
between 15°-25°C
59°-77°F. DO NOT FREEZE.
Rx only



BAUSCH
& LOMB
N.D. 2424-190-1

Litemax
STERILE OPHTHALMIC SUSPENSION 0.5%
2.5 mL
SAMPLE-NOT FOR RESALE

EACH mL CONTAINS: ACTIVE
Lidocaine Hydrochloride 5 mg (0.5%),
PRESERVATIVE ADDED
Benzalkonium Chloride 0.01%

DO NOT USE IF NECKBAND
IMPRINTED WITH "Protective Seal"
AND YELLOW CAP IS NOT INTACT

FOR OPHTHALMIC USE ONLY

Mfd. by Bausch & Lomb
Pharmaceuticals, Inc. Tampa, FL 33637
under Agreement with Pharmacia Corp.

CORE 29995 SAMPLE LABEL

4/C: PMS 197, PMS Violet, Cyan, Black

DIMENSIONS: 3 1/8" x 13/16"

3/4" unvarnish area at left

L-1605

ART IS AT 100%

PHARMACODE#683

APPEARS THIS WAY
ON ORIGINAL

SHAKE VIGOROUSLY
BEFORE USING.
USUAL DOSAGE:
See Package insert.
Storage: Store upright
between 15°-25°C
59°-77°F. DO NOT FREEZE.
Rx only



BAUSCH
& LOMB
NDC 24304 0000

Litemax
Lidocaine Hydrochloride Ophthalmic Suspension 0.5%
STERILE OPHTHALMIC SUSPENSION
5 mL

EACH mL CONTAINS: ACTIVE
Lidocaine Hydrochloride 5 mg (0.5%),
PRESERVATIVE ADDED
Benzalkonium Chloride 0.01%.

DO NOT USE IF NECKBAND
IMPRINTED WITH "Protective Seal"
AND YELLOW CAP IS NOT INTACT.

FOR OPHTHALMIC USE ONLY.

Mfd. by Bausch & Lomb
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CORE 29907 LABEL

4/C: PMS 197, PMS Violet, Cyan, Black

DIMENSIONS: 3 1/8" x 13/16"

3/4" unvarnish area at left

L-1605

ART IS AT 100%

PHARMACODE#681

APPEARS THIS WAY
ON ORIGINAL

SHAKE VIGOROUSLY BEFORE
USING USUAL DOSAGE.
See Package insert
Storage: Store upright
between 5°-25°C (50°-77°F)
DO NOT FREEZE
Rx only



BAUSCH
& LOMB
NDC 24208-249-10
Lotemax
bimatoprost ophthalmic suspension 0.03%
STERILE OPHTHALMIC SUSPENSION
10 mL

EACH mL CONTAINS ACTIVE
Lidocaine Hydrochloride 5 mg (0.5%);
PRESERVATIVE ADDED:
Benzalkonium Chloride 0.01%

DO NOT USE IF NECKBAND
IMPRINTED WITH "Protective Seal"
AND YELLOW CAP IS NOT INTACT

Mfd. by Bausch & Lomb
Pharmaceuticals Inc. Tampa, FL 33637
under Agreement with Pharmacia Corp.

402900 104652 R 7/90 80

CORE 29909 LABEL

4/C: PMS 197, PMS Violet, Cyan, Black

DIMENSIONS: 3 3/8" x 0.711"

- 5/8" unvarnish area at left

L-1614

ART IS AT 100%

PHARMACODE#680

APPEARS THIS WAY
ON ORIGINAL

SHAKE VIGOROUSLY
BEFORE USING.
USUAL DOSAGE:
See Package Insert.
KEEP OUT OF REACH
OF CHILDREN.

Storage: Store upright
between 15°-25°C (59°-77°F)
DO NOT FREEZE

Rx only
FOR OPHTHALMIC
USE ONLY.

BAUSCH
& LOMB
NDC 24208-299-15

Litemax
diethyl carbonate ophthalmic suspension 0.5%
STERILE OPHTHALMIC SUSPENSION

EACH mL CONTAINS
ACTIVE: Leuprolide Enanthate
5 mg (0.5%)
INACTIVES: Edetate Disodium,
Glycerin, Polydioxanone, Purified Water,
and Tylosin. Hydrochloric Acid
and/or Sodium Hydroxide may
be added to adjust the pH. The pH of
the suspension is 3.5 to 6.0 and the
osmolality is 250 to 310 mOsmol/kg.
PRESERVATIVE ADDED:
Benzalkonium Chloride 0.01%.

DO NOT USE IF NECKBAND
IMPRINTED WITH Protective Seal
AND YELLOW cap IS NOT INTACT

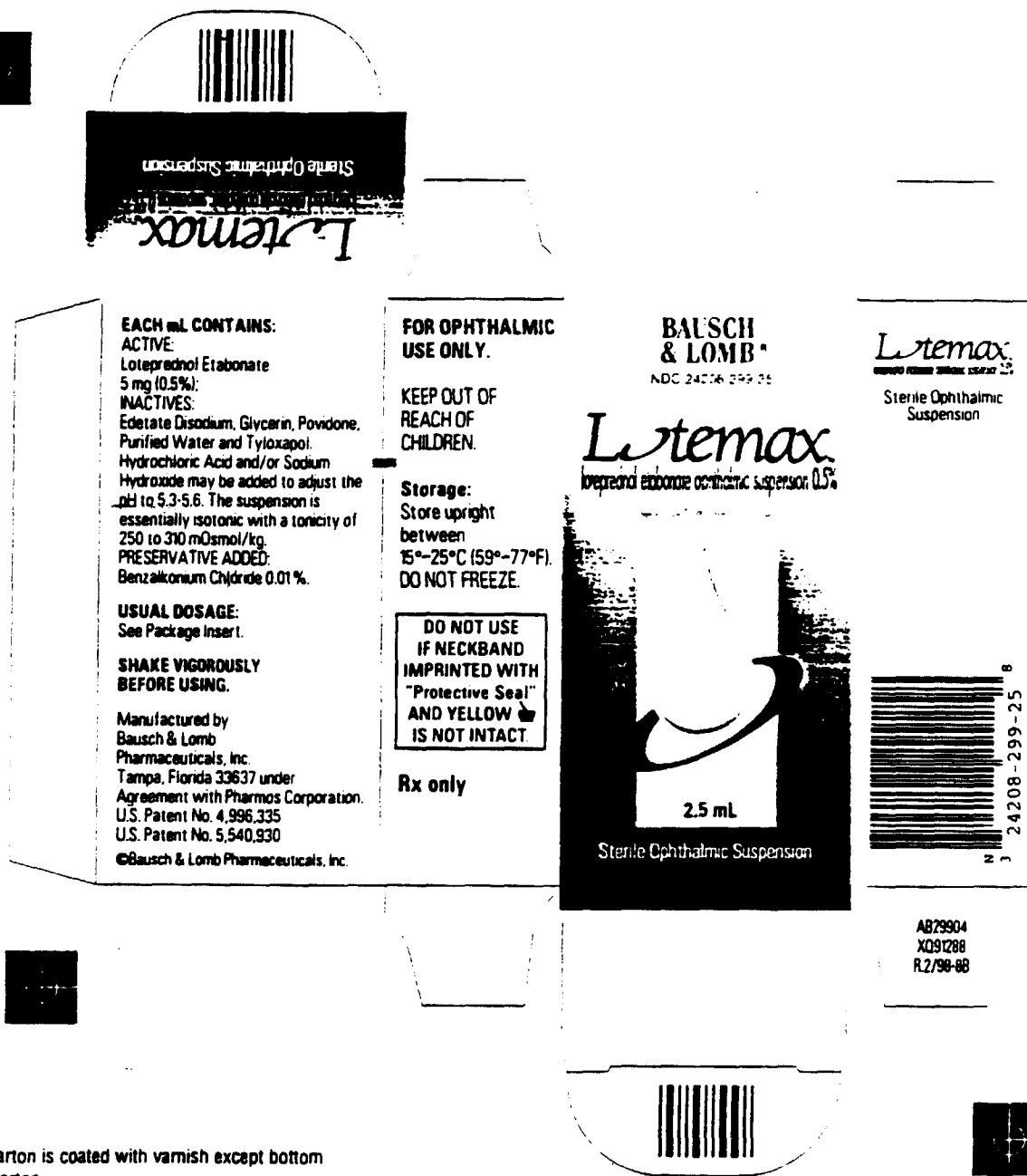
Manufactured by Bausch & Lomb
Pharmaceuticals, Inc.
Tampa, FL 33637 under Agreement
with Pharmacia Corporation
©Bausch & Lomb Pharmaceuticals, Inc.



15 mL

CORE 29911
4/C: PMS 197, PMS Violet, Cyan, Black
DIMENSIONS: 3 3/8" x 1 3/8" 5/8" Non uv @ left
L-1604
ART IS AT 100%
PHARMACODE#992

APPEARS THIS WAY
ON ORIGINAL



Entire carton is coated with varnish except bottom flap of carton.

CORE 29904

4/C: PMS 197, PMS Violet, Cyan, Black

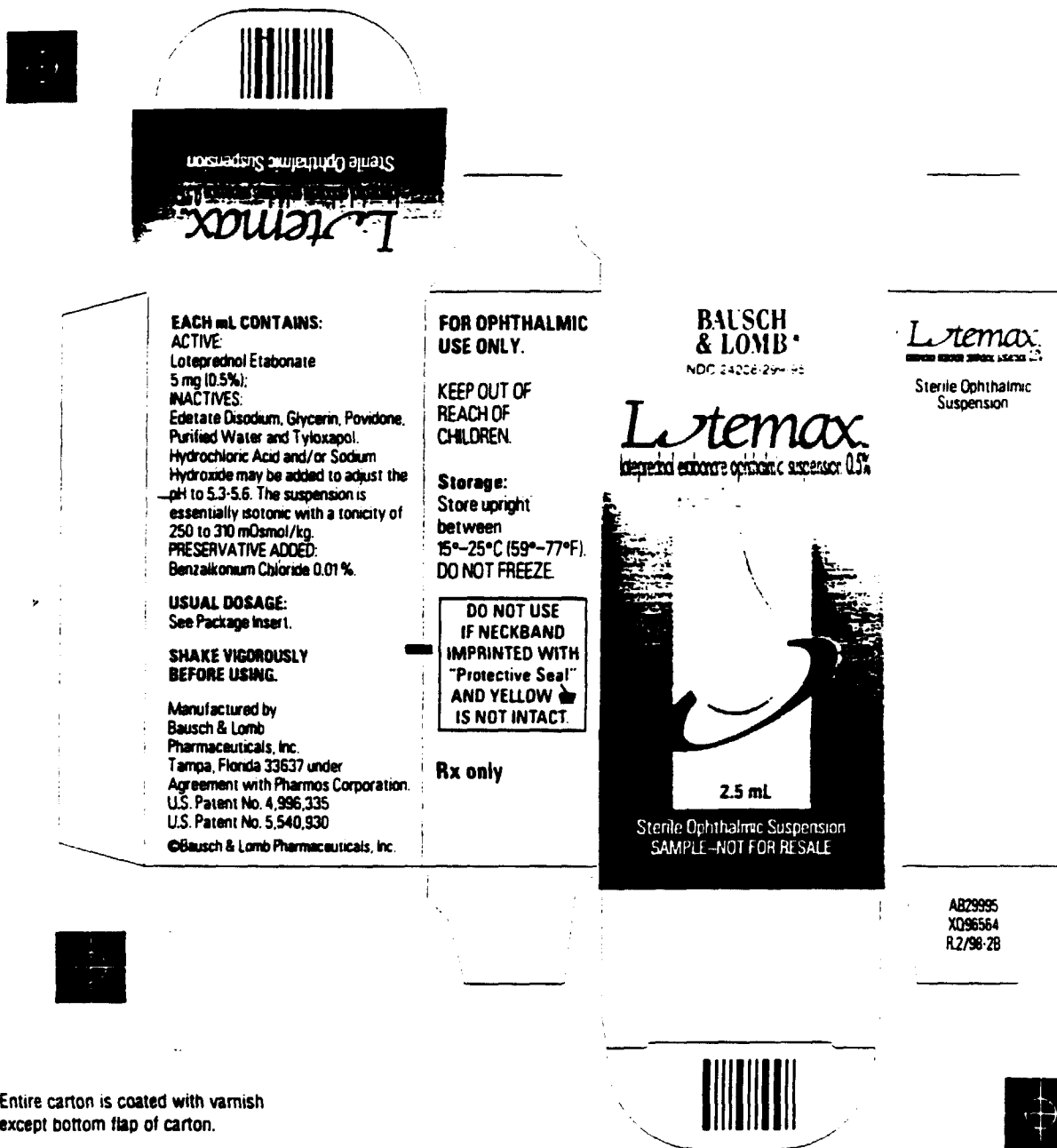
DIMENSIONS: 1 5/8" x 1 1/16" x 3 3/8"

L-2004

ART IS AT 100%

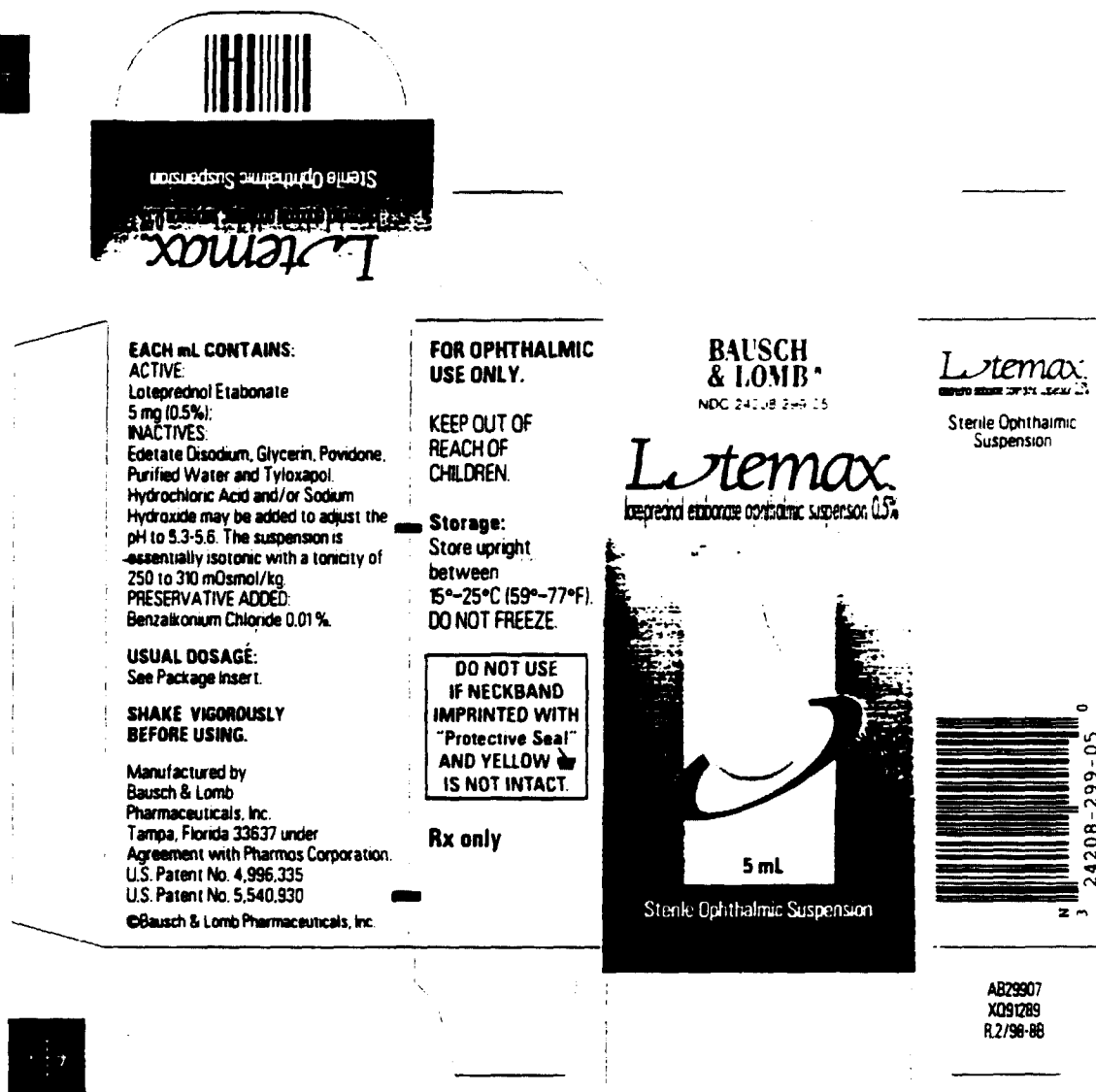
PHARMACODE#2449

SCANNER BAR POSITION: 2.4375" (39)



Entire carton is coated with varnish
 except bottom flap of carton.

CORE 29995
 4/C: PMS 197, PMS Violet, Cyan, Black
 DIMENSIONS: 1 5/8" x 1 1/16" x 3 3/8"
 L-2004
 ART IS AT 100%
 PHARMACODE#2448
 SCANNER BAR POSITION: 3" (48)



Entire carton is coated with varnish except bottom flap of carton.

CORE 29907

4/C: PMS 197, PMS Violet, Cyan, Black

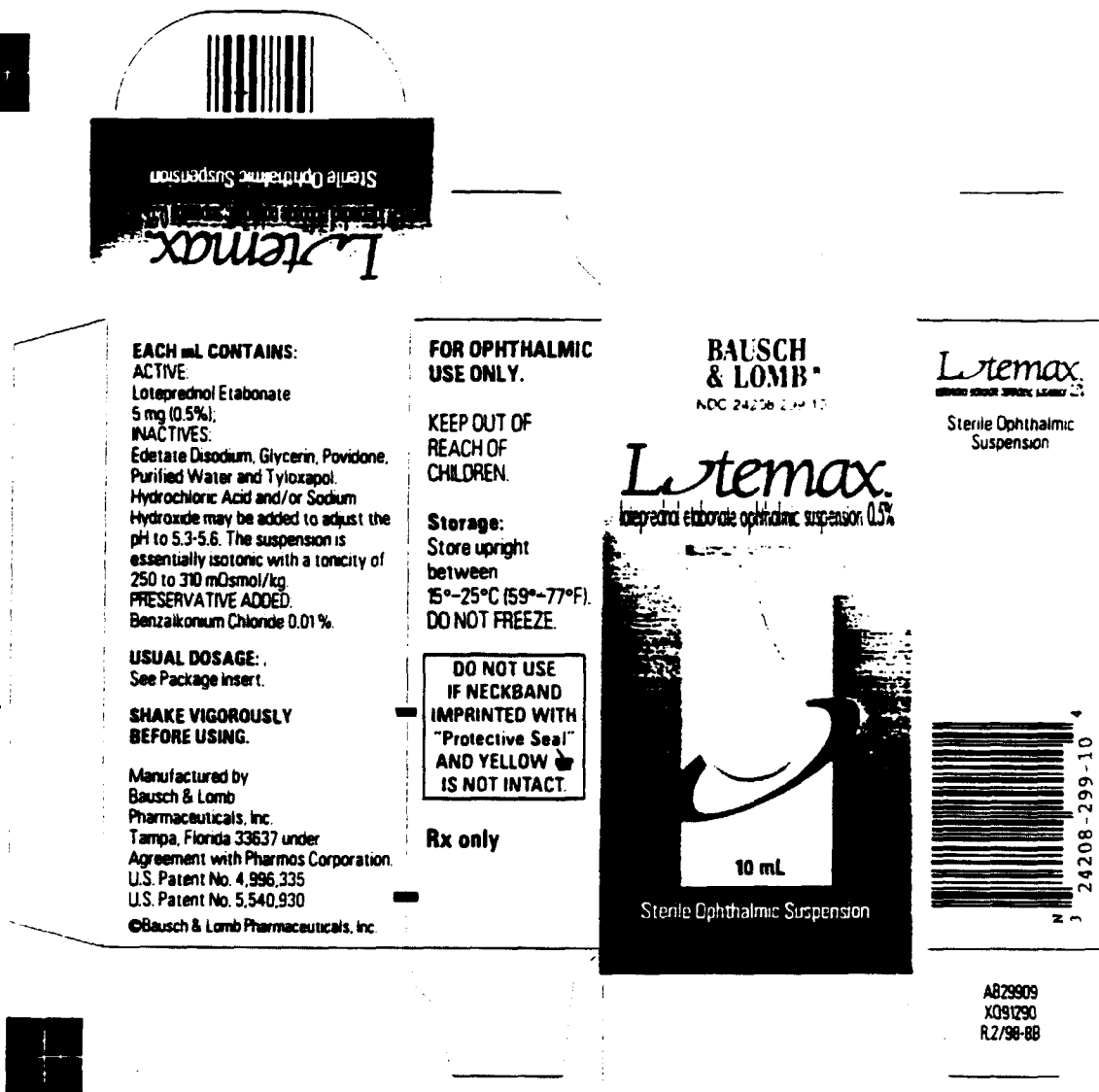
DIMENSIONS: 1 5/8" x 1 1/16" x 3 3/8"

L-2004

ART IS AT 100%

PHARMACODE#2500

SCANNER BAR POSITION: 0.25" (4) & 2.25" (36)



Entire carton is coated with varnish except bottom flap of carton.

CORE 29909

4/C: PMS 197, PMS Violet, Cyan, Black

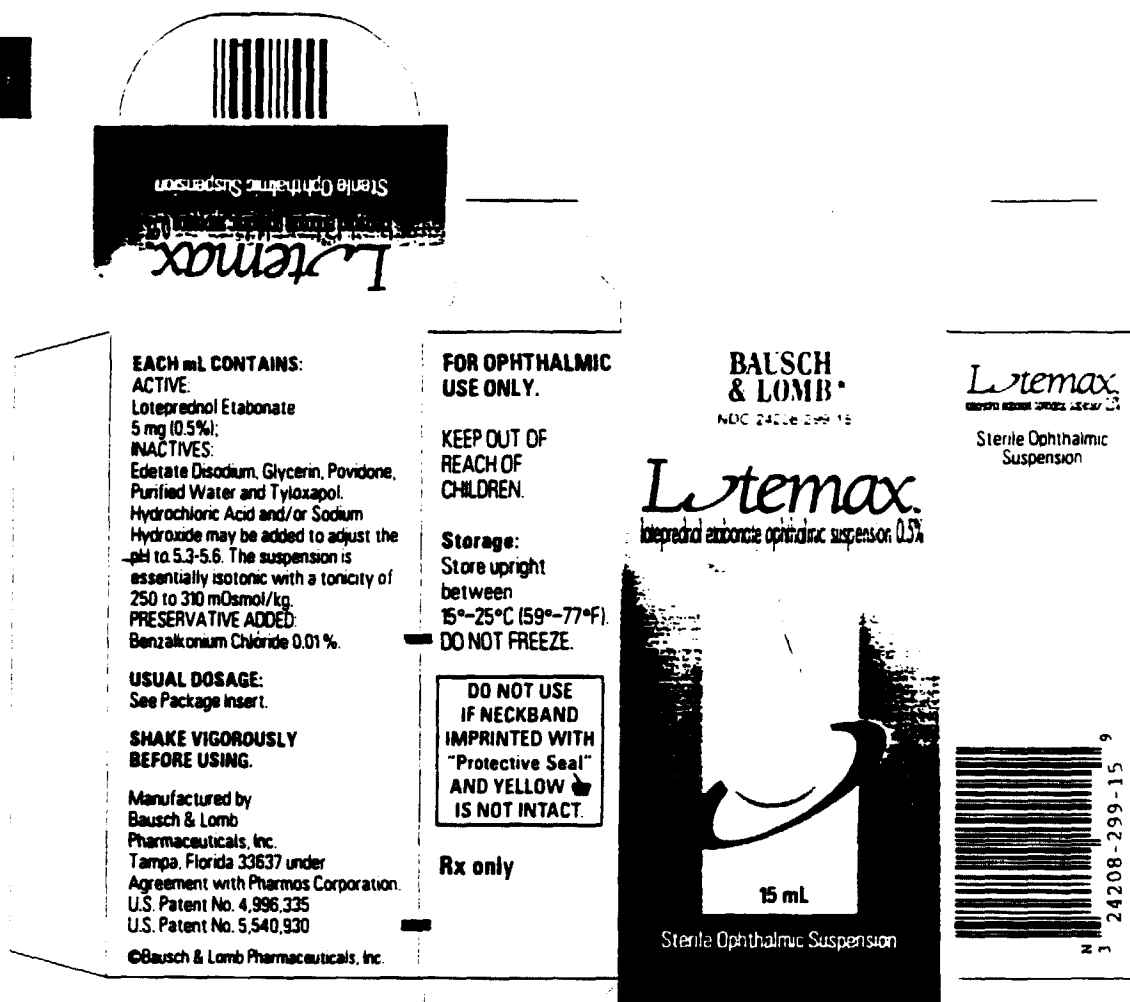
DIMENSIONS: 1 5/8" x 1 1/16" x 3 3/8"

L-2004

ART IS AT 100%

PHARMACODE#2501

SCANNER BAR POSITION: 0.25" (4) & 1.25" (20)



Entire carton is coated with varnish except bottom flap of carton.

CORE 29911

4/C: PMS 197, PMS Violet, Cyan, Black

DIMENSIONS: 1 5/8" x 1 1/16" x 3 3/8"

L-2004

ART IS AT 100%

PHARMACODE#2502

SCANNER BAR POSITION: 0.25" (4) & 1.75" (28)

AB29911
X091291
R.2/98-88

SHAKE VIGOROUSLY
BEFORE USING.
USUAL DOSAGE:
See Package Insert.
Storage: Store upright
between 15°-25°C.
(59°-77°F). DO NOT FREEZE.
Rx only



BAUSCH
& LOMB
NY 10018-2991

Litemax
Imprinted redoxon ophthalmic suspension (0.5%)
STERILE OPHTHALMIC SUSPENSION
2.5 mL

EACH mL CONTAINS: ACTIVE
Leopoldine Eladonate 5 mg (0.5%)
PRESERVATIVE ADDED
Benzalkonium Chloride 0.01%

DO NOT USE IF NECKBAND
IMPRINTED WITH "Protective Seal"
AND YELLOW CAP IS NOT INTACT

FOR OPHTHALMIC USE ONLY

Mkt. by Bausch & Lomb
Pharmaceuticals, Inc. Tampa, FL 33637
under Agreement with Pharmas Corp.

CORE 29904 LABEL

4/C: PMS 197, PMS Violet, Cyan, Black

DIMENSIONS: 3 1/8" x 13/16"

3/4" unvarnish area at left

L-1605

ART IS AT 100%

PHARMACODE#682

APPEARS THIS WAY
-- ON ORIGINAL