


NDA 20-439/S-011

Page 3

5 mL Carton Label, 0.25%



**JAAKKOO-TAARA OY**  
 VEDOKSEN VÄRIT  
 107607  
 3220647-3  
 14.04.2004


HYVÄKSYTÄÄN  
 KORJAUSTEN JÄLKEEN

UUSI VEDOS

287  
 2995


HYVÄKSYTÄÄN  
 PAINETTAVAKSI

VEDOKSEN TARKASTI  
  
 \_\_\_ / \_\_\_ 200 \_\_\_  
  
 STANSSI  
 VÄRIT OVAT VIITTEELLISIÄ

  
 (TIMOLOL OPTHALMIC SOLUTION) 0.25%

Lot No.:  
Exp. Date:

NDC 68669-522-05



68669-522-05  
0

**BETIMOL**<sup>®</sup>  
 (TIMOLOL OPTHALMIC SOLUTION) 0.25%

*Timolol equivalent (timolol hemihydrate 2.56 mg/mL)*

**Rx Only**

**5 mL**


**VISTAKON**<sup>®</sup>  
 PHARMACEUTICALS, LLC


**FOR TOPICAL APPLICATION IN THE EYE**

Usual Adult Dose: 1 drop in the eye once or twice daily. See accompanying prescribing information.

Protect from light. Store between 15-30°C (59-86°F). Do not freeze.


3220647/3





NDA 20-439/S-011  
 Page 4

10 mL Carton Label, 0.25%





**JAAKKO-TAARA OY**  
 VEDOKSEN VÄRIT  
 107604  
 3220649-3  
 14.04.2004


HYVÄKSYTÄÄN  
 KORJAUSTEN JÄLKEEN  
 HYVÄKSYTÄÄN  
 PAINETTAVAKSI

UUSI VEDOS

VEDOKSEN TARKASTI \_\_\_\_\_

 287

 2995


 STANSSI

\_\_\_\_ / \_\_\_\_ 200\_\_

VÄRIT OVAT VIITTEELLISIX

Exp. Date: \_\_\_\_\_

Lot No.: \_\_\_\_\_



N  
68669-522-10  
4

NDC 68669-522-10

**BETIMOL<sup>®</sup>**  
 (TIMOLOL OPTHALMIC  
 SOLUTION) 0.25%

*Timolol equivalent (timolol  
 hemihydrate 2.56 mg/mL)*

**Rx Only**

**10 mL**


**VISTAKON<sup>®</sup>**  
 PHARMACEUTICALS, LLC


**FOR TOPICAL APPLICATION IN  
 THE EYE**

**Usual Adult Dose:** 1 drop in  
 the eye once or twice daily. See  
 accompanying prescribing  
 information.

Protect from light.  
 Store between 15-30°C  
 (59-86°F).  
 Do not freeze.


3220649/3





NDA 20-439/S-011  
 Page 5

15 mL Carton Label, 0.25%





**JAAKKOO-TAARA OY**  
 VEDOKSEN VÄRIT  
 107599  
 3220651-3  
 14.04.2004


HYVÄKSYTTÄXN  
 KORJAUSTEN JÄLKEEN

UUSI VEDOS

HYVÄKSYTTÄXN  
 PAINETTAVAKSI


VEDOKSEN TARKASTI  
 \_\_\_\_\_  
 \_\_\_\_ / \_\_\_\_ 200 \_\_\_\_

 287  
 2995

 STANSSI

VEDOKSEN TARKASTI

VÄRIT OVAT VIITTEELLISIX



(TIMOLOL OPTHALMIC  
 SOLUTION) 0.25%  
**BETIMOL®**

Lot No.: \_\_\_\_\_  
 Exp. Date: \_\_\_\_\_

This product is manufactured sterile and should be dispensed in the original unopened bottle. Patients should be instructed on the precautions to avoid contamination.

**Each mL Contains:**  
 2.5 mg timolol equivalent to 2.56 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative.

**Manufactured by:**  
 Santen Oy  
 P.O. Box 33  
 FIN-33721 Tampere, Finland

**Marketed by:**  
 VISTAKON® Pharmaceuticals, LLC  
 Jacksonville, FL 32256 USA

NDC 68669-522-15

**BETIMOL®**  
 (TIMOLOL OPTHALMIC  
 SOLUTION) 0.25%

*Timolol equivalent (timolol hemihydrate 2.56 mg/mL)*

**Rx Only**

**15 mL**


**VISTAKON®**  
 PHARMACEUTICALS, LLC


**FOR TOPICAL APPLICATION IN THE EYE**

**Usual Adult Dose:** 1 drop in the eye once or twice daily. See accompanying prescribing information.

Protect from light.  
 Store between 15-30°C (59-86°F).  
 Do not freeze.

3220651/3

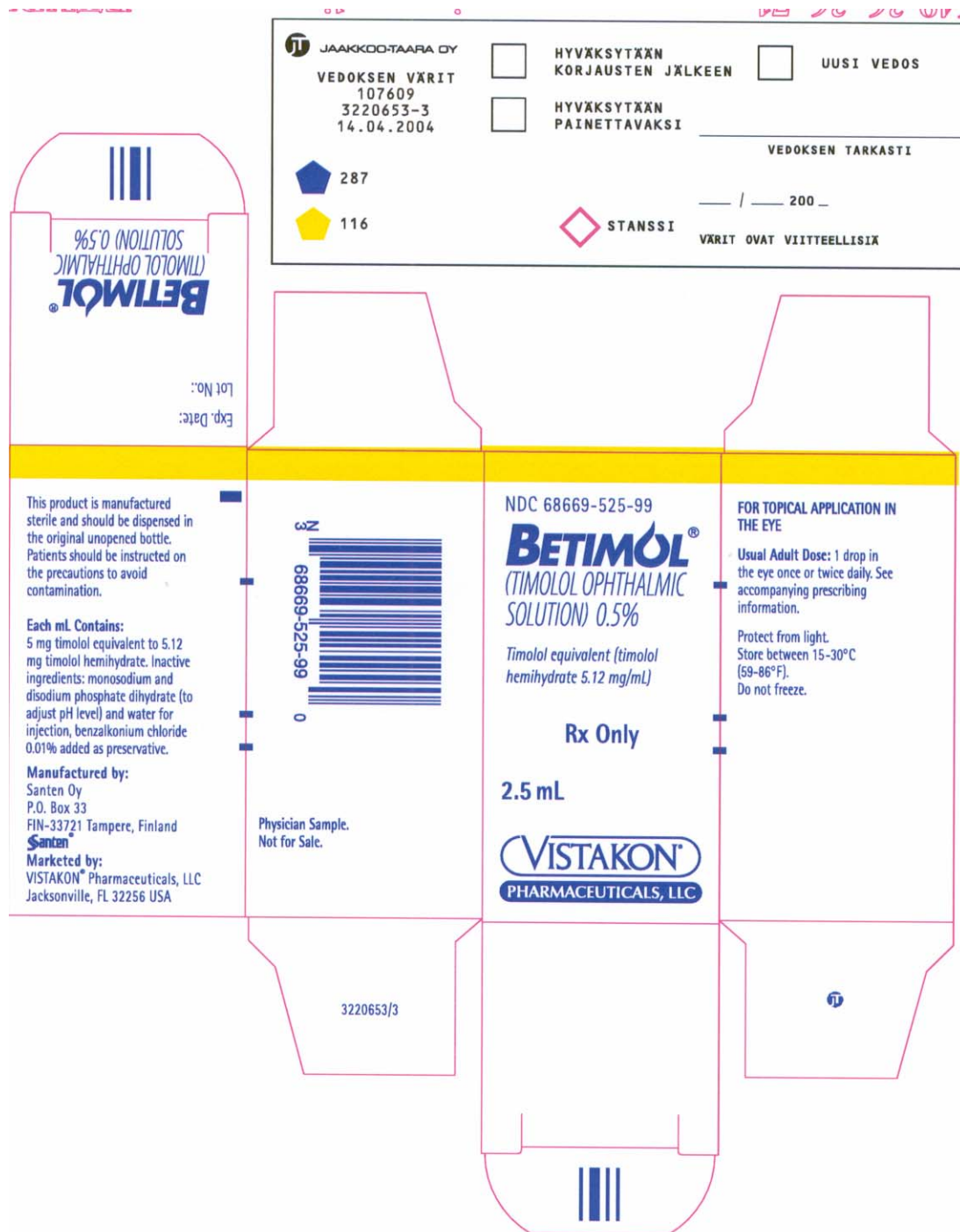




NDA 20-439/S-011

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2.5 mL Carton Label, 0.5%



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5 mL Carton Label, 0.5%



JAAKKOO-TAARA OY

VEDOKSEN VÄRIT  
107601  
3220655-3  
14.04.2004

HYVÄKSYTÄÄN  
KORJAUSTEN JÄLKEEN

UUSI VEDOS

 287  
 116

 STANSSI

VEDOKSEN TARKASTI

— / — 200 —

VÄRIT OVAT VIITTEELLISIA

Exp. Date:

Lot No.:



68669-525-05

NDC 68669-525-05

**BETIMOL**<sup>®</sup>  
(TIMOLOL OPHTHALMIC SOLUTION) 0.5%

*Timolol equivalent (timolol hemihydrate 5.12 mg/mL)*

**Rx Only**

5 mL

**VISTAKON**<sup>®</sup>  
PHARMACEUTICALS, LLC

**FOR TOPICAL APPLICATION IN THE EYE**

**Usual Adult Dose:** 1 drop in the eye once or twice daily. See accompanying prescribing information.

Protect from light.  
Store between 15-30°C (59-86°F).  
Do not freeze.

This product is manufactured sterile and should be dispensed in the original unopened bottle. Patients should be instructed on the precautions to avoid contamination.

**Each mL Contains:**  
5 mg timolol equivalent to 5.12 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative.

**Manufactured by:**  
Santen Oy  
P.O. Box 33  
FIN-33721 Tampere, Finland

**Marketed by:**  
VISTAKON<sup>®</sup> Pharmaceuticals, LLC  
Jacksonville, FL 32256 USA

3220655/3



NDA 20-439/S-011  
 Page 8

10 mL Carton Label, 0.5%

**JAAKKO-TAARA OY**  
 VEDOKSEN VÄRIT  
 107612  
 3220657-3  
 14.04.2004

HYVÄKSYTÄÄN  
KORJAUSTEN JÄLKEEN

HYVÄKSYTÄÄN  
PAINETTAVAKSI

UUSI VEDOS

VEDOKSEN TARKASTI \_\_\_\_\_

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STANSSI

VÄRIT OVAT VIITTEELLISII

287

116

**BETIMOL®**  
(TIMOLOL OPTHALMIC SOLUTION) 0.5%

Exp. Date:  
Lot No.:

This product is manufactured sterile and should be dispensed in the original unopened bottle. Patients should be instructed on the precautions to avoid contamination.

**Each mL Contains:**  
 5 mg timolol equivalent to 5.12 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative.

**Manufactured by:**  
 Santen Oy  
 P.O. Box 33  
 FIN-33721 Tampere, Finland

**Marketed by:**  
 VISTAKON® Pharmaceuticals, LLC  
 Jacksonville, FL 32256 USA

NDC 68669-525-10

68669-525-10

NDC 68669-525-10

**BETIMOL®**  
(TIMOLOL OPTHALMIC SOLUTION) 0.5%

*Timolol equivalent (timolol hemihydrate 5.12 mg/mL)*

**Rx Only**

10 mL

**VISTAKON®**  
PHARMACEUTICALS, LLC

**FOR TOPICAL APPLICATION IN THE EYE**


**Usual Adult Dose:** 1 drop in the eye once or twice daily. See accompanying prescribing information.

Protect from light.  
 Store between 15-30°C (59-86°F).  
 Do not freeze.

3220657/3

NDA 20-439/S-011  
 Page 9



15 mL Carton Label, 0.5%



**JAAKKO-TAARA OY**  
 VEDOKSEN VÄRIT  
 107614  
 3220659-3  
 14.04.2004

HYVÄKSYTÄÄN  
 KORJAUSTEN JÄLKEEN


UUSI VEDOS


 287  
 116

HYVÄKSYTÄÄN  
 PAINETTAVAKSI

VEDOKSEN TARKASTI

\_\_\_ / \_\_\_ 200\_\_

 STANSSI  
 VÄRIT OVAT VIITTEELLISIX



**BETIMOL<sup>®</sup>**  
 (TIMOLOL OPTHALMIC  
 SOLUTION) 0.5%

Exp. Date:  
 Lot No.:

NDC 68669-525-15

**BETIMOL<sup>®</sup>**  
 (TIMOLOL OPTHALMIC  
 SOLUTION) 0.5%

*Timolol equivalent (timolol  
 hemihydrate 5.12 mg/mL)*

**Rx Only**

15 mL


**VISTAKON<sup>®</sup>**  
 PHARMACEUTICALS, LLC

**FOR TOPICAL APPLICATION IN  
 THE EYE**

*Usual Adult Dose: 1 drop in  
 the eye once or twice daily. See  
 accompanying prescribing  
 information.*

*Protect from light.  
 Store between 15-30°C  
 (59-86°F).  
 Do not freeze.*

3  
 68669-525-15  
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This product is manufactured sterile and should be dispensed in the original unopened bottle. Patients should be instructed on the precautions to avoid contamination.


**Each mL Contains:**  
 5 mg timolol equivalent to 5.12 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative.

**Manufactured by:**  
 Santen Oy  
 P.O. Box 33  
 FIN-33721 Tampere, Finland

**Marketed by:**  
 VISTAKON<sup>®</sup> Pharmaceuticals, LLC  
 Jacksonville, PL 32256 USA

3220659/3





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5 mL Container Label, 0.25%

3220646/3

**Rx Only**  
FOR TOPICAL APPLICATION  
IN THE EYE  
**Usual Adult Dose:** 1 drop in the eye once or twice daily. See accompanying prescribing information.  
Store between 15-30°C (59-86°F).  
Do not freeze.

NDC 68669-522-05

**BETIMOL<sup>®</sup>**  
(TIMOLOL OPHTHALMIC SOLUTION) 0.25%

Timolol equivalent (timolol hemihydrate 2.56 mg/mL) **5 mL**

**VISTAKON<sup>®</sup>**  
PHARMACEUTICALS, LLC

**Each mL Contains:** 2.5 mg timolol equivalent to 2.56 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative. Protect from light.  
**Manufactured by: Santen**  
Santen Oy  
P.O. Box 33, FIN-33721 Tampere, Finland  
**Marketed by: VISTAKON<sup>®</sup>**  
Pharmaceuticals, LLC  
Jacksonville, FL 32256 USA

Lot:  
Exp:



10 mL Container Label, 0.25%

3220648/3

**Rx Only**  
FOR TOPICAL APPLICATION  
IN THE EYE  
**Usual Adult Dose:** 1 drop in the eye once or twice daily. See accompanying prescribing information.  
Store between 15-30°C (59-86°F).  
Do not freeze.

NDC 68669-522-10

**BETIMOL<sup>®</sup>**  
(TIMOLOL OPHTHALMIC SOLUTION) 0.25%

Timolol equivalent (timolol hemihydrate 2.56 mg/mL) **10 mL**

**VISTAKON<sup>®</sup>**  
PHARMACEUTICALS, LLC

**Each mL Contains:** 2.5 mg timolol equivalent to 2.56 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative. Protect from light.  
**Manufactured by: Santen**  
Santen Oy  
P.O. Box 33, FIN-33721 Tampere, Finland  
**Marketed by: VISTAKON<sup>®</sup>**  
Pharmaceuticals, LLC  
Jacksonville, FL 32256 USA

Lot:  
Exp:



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15 mL Container Label, 0.25%

3220650/3

**Rx Only**  
**FOR TOPICAL APPLICATION**  
**IN THE EYE**  
**Usual Adult Dose:** 1 drop in the eye once or twice daily. See accompanying prescribing information.  
Store between 15-30°C (59-86°F).  
Do not freeze.

NDC 68669-522-15

**BETIMOL**<sup>®</sup>  
(TIMOLOL OPHTHALMIC SOLUTION) 0.25%

*Timolol equivalent (timolol hemihydrate 2.56 mg/mL)*

**15 mL**

**VISTAKON**<sup>®</sup>  
PHARMACEUTICALS, LLC

**Each mL Contains:** 2.5 mg timolol equivalent to 2.56 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative. Protect from light.

**Manufactured by: Santen**<sup>®</sup>  
Santen Oy  
P.O. Box 33, FIN-33721  
Tampere, Finland

**Marketed by: VISTAKON**<sup>®</sup>  
Pharmaceuticals, LLC  
Jacksonville, FL 32256 USA

Lot:  
Exp:



2.5 mL Container Label, 0.5%

3220652/3

**Rx Only**  
**FOR TOPICAL APPLICATION**  
**IN THE EYE**  
**Usual Adult Dose:** 1 drop in the eye once or twice daily. See accompanying prescribing information.  
Store between 15-30°C (59-86°F).  
Do not freeze.

NDC 68669-525-99

**BETIMOL**<sup>®</sup>  
(TIMOLOL OPHTHALMIC SOLUTION) 0.5%

*Timolol equivalent (timolol hemihydrate 5.12 mg/mL)*

**2.5 mL**

**VISTAKON**<sup>®</sup>  
PHARMACEUTICALS, LLC

**Each mL Contains:** 5 mg timolol equivalent to 5.12 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative. Protect from light.

**Manufactured by: Santen**<sup>®</sup>  
Santen Oy  
P.O. Box 33, FIN-33721 Tampere, Finland

**Marketed by: VISTAKON**<sup>®</sup>  
Pharmaceuticals, LLC  
Jacksonville, FL 32256 USA

Lot:  
Exp:



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5 mL Container Label, 0.5%

3220654/3

**Rx Only**  
FOR TOPICAL APPLICATION  
IN THE EYE  
**Usual Adult Dose:** 1 drop in  
the eye once or twice daily.  
See accompanying prescribing  
information.  
Store between 15-30°C (59-86°F).  
Do not freeze.

NDC 68669-525-05

**BETIMOL**<sup>®</sup>  
(TIMOLOL OPHTHALMIC  
SOLUTION) 0.5%

*Timolol equivalent (timolol  
hemihydrate 5.12 mg/mL)* **5 mL**

**Each mL Contains:** 5 mg timolol  
equivalent to 5.12 mg timolol  
hemihydrate. Inactive ingredients:  
monosodium and disodium  
phosphate dihydrate (to adjust pH  
level) and water for injection,  
benzalkonium chloride 0.01% added  
as preservative. Protect from light.

**Manufactured by: Santen**<sup>®</sup>  
Santen Oy  
P.O. Box 33, FIN-33721 Tampere,  
Finland  
**Marketed by: VISTAKON**<sup>®</sup>  
Pharmaceuticals, LLC  
Jacksonville, FL 32256 USA

Lot:  
Exp:



10 mL Container Label, 0.5%

3220656/3

**Rx Only**  
FOR TOPICAL APPLICATION  
IN THE EYE  
**Usual Adult Dose:** 1 drop in the  
eye once or twice daily. See  
accompanying prescribing  
information.  
Store between 15-30°C (59-86°F).  
Do not freeze.

NDC 68669-525-10

**BETIMOL**<sup>®</sup>  
(TIMOLOL OPHTHALMIC  
SOLUTION) 0.5%

*Timolol equivalent (timolol  
hemihydrate 5.12 mg/mL)* **10 mL**

**Each mL Contains:** 5 mg  
timolol equivalent to 5.12 mg  
timolol hemihydrate. Inactive  
ingredients: monosodium and  
disodium phosphate dihydrate  
(to adjust pH level) and water  
for injection, benzalkonium  
chloride 0.01% added as  
preservative. Protect from light.

**Manufactured by: Santen**<sup>®</sup>  
Santen Oy  
P.O. Box 33, FIN-33721  
Tampere, Finland  
**Marketed by: VISTAKON**<sup>®</sup>  
Pharmaceuticals, LLC  
Jacksonville, FL 32256 USA

Lot:  
Exp:



NDA 20-439/S-011

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15 mL Container Label, 0.5%

3220658/3

**Rx Only**  
**FOR TOPICAL APPLICATION**  
**IN THE EYE**  
**Usual Adult Dose:** 1 drop in the eye once or twice daily. See accompanying prescribing information.  
Store between 15-30°C (59-86°F).  
Do not freeze.

NDC 68669-525-15

**BETIMOL<sup>®</sup>**  
**(TIMOLOL OPHTHALMIC SOLUTION) 0.5%**  
*Timolol equivalent (timolol hemihydrate 5.12 mg/mL)*

**15 mL**

**VISTAKON<sup>®</sup>**  
**PHARMACEUTICALS, LLC**

**Each mL Contains:** 5 mg timolol equivalent to 5.12 mg timolol hemihydrate. Inactive ingredients: monosodium and disodium phosphate dihydrate (to adjust pH level) and water for injection, benzalkonium chloride 0.01% added as preservative. Protect from light.  
**Manufactured by: Santen<sup>®</sup>**  
Santen Oy  
P.O. Box 33, FIN-33721  
Tampere, Finland  
**Marketed by: VISTAKON<sup>®</sup>**  
Pharmaceuticals, LLC  
Jacksonville, FL 32256 USA

Lot:  
Exp:

