

HFA 305

Date of Approval NOV 6 2001

FREEDOM OF INFORMATION SUMMARY

ANADA 200-301

Indication for use: Privasan™ Antiseptic Ointment is used as a topical antiseptic ointment for surface wounds on dog's, cats, and horses.

Sponsored by:

First Priority, Inc.
1585 Todd Farm Drive
Elgin, Illinois 60 123

FOIS 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA: 200-301

Sponsor: First Priority, Inc.
1585 Todd Farm Drive
Elgin, Illinois 60123

Generic Name: Chlorhexidine Antiseptic Ointment

Trade Name: Privasan™ Antiseptic Ointment

Dosage Form: Topical ointment

How Supplied: 1 oz (28 g) tubes, 7 oz (198 g) jars & 16 oz (453 g) jars

How Dispensed: OTC

Amount of Active Ingredients: 1 % chlorhexidine acetate in a hydrophilic ointment

Route of Administration: Topical

Species: -Dogs, cats and horses

Pharmacological Category: Antiseptic

Labeled Dosage & Indications for Use: Use as a topical antiseptic ointment for surface wounds on dogs, cats and horses.

Pioneer Product! Nolvasan® Antiseptic Ointment
"Listed Product: NADA 09-782
(Fort Dodge Animal Health)

2. TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug

(pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. Ordinarily the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October, 2000).

Based upon the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver on June 17, 1999, from conducting an *in vivo* bioequivalence study for Privasan Antiseptic Ointment. The generic and pioneer products are topical ointments, which contain the same active ingredients in the same concentrations as the pioneer, and similar inactive ingredients in a hydrophilic ointment base. The pioneer product, Nolvasan® Antiseptic Ointment, Fort Dodge Animal Health, NADA 9-782, was approved on March 22, 1955.

3. HUMAN SAFETY:

Chlorhexidine diacetate ointment is intended for use only in dogs, cats and horses, which are nonfood animals.

Human Warnings are provided on the product label as follows:

“For Animal use only.

Keep Out of Reach of Children.

Not for use in horses intended for food.”

Human Safety Relative to Possession, Handling, and Administration: Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 5 12(b) of the Federal, Food, Drug and Cosmetic (FFD&C) Act satisfies the requirements of section 5 12(n) of the Act and demonstrates that Privasan™ Antiseptic Ointment when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. LABELING:

Attachments:

Pioneer Labeling:

1 oz (28 g) tube
7 oz (198 g) jar
16 Oz (453 g) jar

Generic Labeling:

1 oz (28 g) tube
7 oz (198 g) jar
16 Oz (453 g) jar

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6500.

NDC 0856-X371-01

Nolvasan
Antiseptic Ointment
1% Chlorhexidine
acetate in a Hydrophilic
Ointment base which
contains 10% stearyl
alcohol

Nolvasan[®]
Antiseptic
Ointment



CAUTION: Not to be used on horses
intended for use as food. In case of
deep or puncture wounds or serious
burns consult veterinarian. If red-
ness, irritation or swelling persists
or increases, discontinue use and
consult veterinarian.
Store at controlled room tempera-
ture 15° to 30°C (59° to 86°F).
Protect from freezing.
See tube crimp for Exp. Date and Lot
No.

SUGGESTED USAGE
Dogs, Cats and Horses

For use as a topical
antiseptic ointment for
surface **wounds. Carefully**
cleanse the wound area and
apply daily.

CAUTION
Keep out of reach
of children.

Fort Dodge Laboratories, Inc.
Fort Dodge, Iowa 50501 USA

Net Wt 1 Oz (28 g)

90184

3711H

NADA 9-782, Approved by FDA

371441 2/80

NDC0856-7371-02

Nolvasan[®]

Antiseptic Ointment



1% Chlorhexidine acetate in a Hydrophilic Ointment base which contains 10% stearyl alcohol

CAUTION
Keep out of reach of children.

Net Wt 7 Oz (198 g)

NADA 009-782, Approved by FDA

SUGGESTED USAGE: Dogs, Cats and Horses - For use as a topical antiseptic ointment for surface wounds. Carefully cleanse the wound area and apply daily.

Store at controlled room temperature 15° to 30°C (59° to 86°F). Protect from freezing.

CAUTION: Not to be used on horses intended for use as food. In case of deep or puncture wounds or serious burns consult veterinarian. If redness, irritation or swelling persists or increases, discontinue use and consult veterinarian.

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

Lot
Exp. Date



0030

SECTION VI
Bioavailability/Bioequivalence
SECTION VII
Components and Composition

NDC0856-7371-03

Nolvasan[®]

Antiseptic Ointment

FORT DODGE[®]

1% Chlorhexidine acetate
in a Hydrophilic Ointment
base which contains
10% stearyl alcohol.

CAUTION
Keep out of reach of children.

Net Wt 16 Oz (453g)

NADA 009-782, Approved by FDA

**SUGGESTED USAGE: Dogs,
Cats and Horses** – For use as a
topical antiseptic ointment for sur-
face wounds. Carefully cleanse the
wound area and apply daily.

Store at controlled room tempera-
ture 15° to 30°C (59° to 86°F).
Protect from freezing.

CAUTION: Not to be used on
horses intended for use as food. In
case of deep or puncture wounds
or serious burns consult veterinar-
ian. If redness, irritation or swelling
persists or increases, discontinue
use and consult veterinarian.

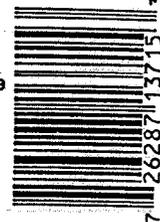
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

Lot 371474
Exp. JAN 01

37156
9126



Lot Exp.



7 26287 13715 3

100% Water Soluble

**Priority
Care**



**Privasan™
Antiseptic Ointment**

1% Chlorhexidine Acetate
in a Hydrophilic Ointment
Base Which Contains
10% Stearyl Alcohol

SUGGESTED USAGE: Dogs, Cats
and Horses: Use as a topical anti-
septic treatment of surface wounds.
Carefully cleanse the wound area
and apply daily.

CAUTION: Not to be used on horses
intended for use as food. In case of
deep or puncture wounds or serious
burns, consult veterinarian. If redness,
irritation or swelling persists or
increases, discontinue use and
consult veterinarian.

STORAGE: Store in controlled room
temperature between 15°-30°C (59°-
86°F). Protect from freezing.

See tube wrap for Lot No. and Exp. Date

Reorder No. CH050PCARE
Rev. 07-01

Manufactured By:
FIRST PRIORITY, INC., Elgin, IL 60123

CAUTION
Keep out of reach
of children

Net Contents: 1 oz. (28 g)



ANADA 200-301. Approved by FDA

NDC# 58829-288-07

Priority Care



SUGGESTED USAGE: Dogs, Cats and Horses. For use as a topical antiseptic ointment for surface wounds. Carefully debride the wound area and apply daily.

CAUTION: If redness, irritation or swelling persists or increases, discontinue use and consult veterinarian.

Privasan™ Antiseptic Ointment

1% Chlorhexidine Acetate in A Hydrophilic Ointment Base Which Contains 10% Stearyl Alcohol

WARNING: Not to be used on horses, ponies, foals or dogs. In case of deep or puncture wounds or serious burns, consult veterinarian.

STORAGE: Store in controlled room temperature between 15°-30°C (59°-86°F). Keep container tightly closed when not in use.

PROTECT FROM FREEZING



Rev. 02-01

For Animal Use Only & Keep Out of Reach of Children
Net Contents: 7 oz. (198 g)

ANADA 200-301. Approved by FDA

NO VARNISH

Order No. CH05PCARE

NDC# 58829-289-16

Priority Care



SUGGESTED USAGE: Dogs, Cats and Horses
For use as a topical antiseptic ointment for surface wounds. Carefully cleanse the wound area and apply daily.

CAUTION: If redness, irritation or swelling persists or increases, discontinue use and consult veterinarian.

Privasan™ Antiseptic Ointment

1% Chlorhexidine Acetate in A Hydrophilic Ointment Base Which Contains 10% Stearyl Alcohol

For Animal Use Only - Keep Out of Reach of Children

Net Contents: 1 lb. (453.6 g)

ANADA 200-301, Approved by FDA

WARNING: Not to be used on horses intended for use as food. In case of deep or puncture wounds or serious burns, consult veterinarian.

STORAGE: Store at controlled room temperature between 15°-30°C (59°-86°F). Keep container tightly closed when not in use.

PROTECT FROM FREEZING

NO VARNISH

Reorder No. CH052PCARE



Rev. 06-01



NDC# 58829-07

Priority Care 

**Privasan™
Antiseptic Ointment**

1% Chlorhexidine Acetate
in a Hydrophilic Ointment
Base Which Contains
10% Stearyl Alcohol.

CAUTION
Keep out of reach
of children

Net Contents: 1 oz. (28 g)

ANADA 200-301, Approved by FDA

SUGGESTED USAGE: Dogs, Cats and Horses. For use as a topical antiseptic ointment for surface wounds. Carefully cleanse the wound area and apply daily.

CAUTION: Not to be used on horses intended for use as food. In case of deep or puncture wounds or serious burns, consult veterinarian. If redness, irritation or swelling persists or increases, discontinue use and consult veterinarian.

STORAGE: Store at controlled room temperature between 15°-30°C (59°-86°F). Protect from freezing.

See tube crimp for Lot No. and Exp. Date

Reorder No. CH050PCARE
Iss. 07-01

Manufactured By:
FIRST PRIORITY, INC., Elgin, IL 60120

POSITION ONLY

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NDC# 58829-288-07

Priority Care 

**Privasan™
Antiseptic Ointment**

1% Chlorhexidine Acetate In A Hydrophilic Ointment
Base Which Contains 10% Stearyl Alcohol.

CAUTION: If redness, irritation or swelling persists or increases, discontinue use and consult veterinarian.

WARNING: Not to be used on horses intended for use as food. In case of deep or puncture wounds or serious burns, consult veterinarian.

STORAGE: Store at controlled room temperature between 15°-30°C (59°-86°F). Keep container tightly closed when not in use.

PROTECT FROM FREEZING

LOT NO. EXP. DATE

NO VARNISH

Reorder No. CH051PCARE

62308 28807

Rev. 08-01

MAKE TIME  OBSERVE LABEL DIRECTIONS

For Animal Use Only • Keep Out of Reach of Children
Net Contents: 7 oz. (198 g)

ANADA 200-301, Approved by FDA

NDC# 58829-298-16

Priority Care 

**Privasan™
Antiseptic Ointment**

1% Chlorhexidine Acetate In A Hydrophilic Ointment
Base Which Contains 10% Stearyl Alcohol.

CAUTION: If redness, irritation or swelling persists or increases, discontinue use and consult veterinarian.

WARNING: Not to be used on horses intended for use as food. In case of deep or puncture wounds or serious burns, consult veterinarian.

STORAGE: Store at controlled room temperature between 15°-30°C (59°-86°F). Keep container tightly closed when not in use.

PROTECT FROM FREEZING

LOT NO. EXP. DATE

NO VARNISH

Reorder No. CH050PCARE

62308 28816

Rev. 06-01

MAKE TIME  OBSERVE LABEL DIRECTIONS

For Animal Use Only • Keep Out of Reach of Children
Net Contents: 1 lb. (453.6 g)

ANADA 200-301, Approved by FDA