F10- f10 antiseptic solution concentrate liquid
Health and Hygiene (Pty) Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

F10 Antiseptic Solution Concentrate

Warnings

Not for use in humans. Keep out of reach of children

Uses

For the treatment and control of upper and lower respiratory tract diseases associated with bacterial, fungal, or viral organisms.

For use as a topical antiseptic for surface wounds.

Direction of use

The concentrate need to be diluted with distilled or saline solution 1:250 prior to use.

Use for Nebulization, nasal and sinus flushing and surface wounds.

See label for further instructions

Packaging label

Front Panel

US231-01 22 ANTISEPTIC SOLUTION CONCENTRATE -200ml- GENERIC FP.jpg

Packaging Label

Back Panel

US231-01 22 ANTISEPTIC SOLUTION CONCENTRATE -200ml- GENERIC BP.jpg

Description:

The active ingredients in F10® brand Antiseptic solution are Benzalkonium chloride and Polyhexanide. Benzalkonium chloride is a biocide of the quaternary ammonium group. Its chemical name is: N-Alkyl-N-benzyl-N,N-dimethylammonium chloride. Polyhexanide is a cationic biocide. Its chemical name is: Poly (hexamethylene biguanide hydrochloride). Each mL of F10® brand Antiseptic Solution contains 54.0 mg of benzalkonium chloride and 4.0 mg of polyhexanide.

Indications:

For the treatment and control of upper and lower respiratory tract disease associated with bacterial, fungal, or viral organisms susceptible to benzalkonium chloride and polyhexanide in raptors, pet birds, captive small mammals, and captive reptiles.

For use as a topical antiseptic for surface wounds on raptors, pet birds, captive

For use as a topical antiseptic for surface wounds on raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

Use only when there is a reasonable certainty that the treated animal will not be consumed by humans or food-producing animals.

Dosage and Administration:
Dilute the concentrate 1:250 with normal saline solution prior to use.

Nebulization:

- To Nebulize the glottis, trachea, lungs and air sacs for individual birds, reptiles and small mammals use a chamber connected to a nebulizing unit capable of producing a particle size smaller than 5µm but which allows the resulting "fog" to build-up inside the chamber within 5 minutes and continue for 20 to 40 minutes. Repeat 2 times a day for 2 to 4 weeks (up to 8 weeks in severe cases) until the signs of illness resolve. In raptors, withhold food for 3 hours after nebulization as crop emptying may be delayed.
- For larger animals or groups of small animals, place them in a suitable sized enclosed room in which a standing fog can be achieved in 5 minutes using a portable electrical atomizer/fogger or a static pressure system capable of producing a particle size of ± 10 to 12µm. Repeat 2 times a day for 2 to 4 weeks (up to 8 weeks in severe cases) until the signs of illness resolve.

Nasal and Sinus Flushing:

- To remove accumulated mucous and inflammatory material in the upper respiratory tract, syringe into the nasal and sinus cavities (consisting of the external nares, operculum, nasal concha, infraorbital sinus and choanal slit) with the animal's head down and mouth open to avoid aspiration and allow drainage out of the oral cavity. This treatment should be repeated daily for 10-14 days until the signs of illness resolve.

LOT NO: **EXP. DATE:**

Packaging Label

Back Panel 2

US231-01 22 ANTISEPTIC SOLUTION CONCENTRATE -200ml- GENERIC BP2.jpg

Surface Wounds:

- For wound irrigation flush as necessary. For skin decontamination apply as a wash or spray and allow to air dry.

Contraindications:

Contraindications:
Do not use with soaps or other chemicals

Warnings:
Not for use in humans. Keep out of reach of children.
If accidentally ingested, do not induce vomiting. Give milk or water to drink.
If accidental eye contact, hold eye open and rinse with water for 10 minutes.
Seek medical help if necessary.

Effectiveness:
The active ingredients Benzalkonium chloride and Polyhexanide act on the cell membrane causing it to rupture, resulting in the loss of essential cell components. Additionally, non-toxic ampholytic surfactants and sequesterants in the drug formulation aid in the penetration of the cell or spore wall. Examples of clinical cases successfully treated with F10® brand Antiseptic Solution include upper respiratory tract disease associated with *Pseudomonas* spp. and *Aspergillus* spp. in birds, upper respiratory tract disease associated with *Pasteurella* spp., *Pseudomonas* spp., *Aspergillus* spp. and *Mycoplasma* spp. in small mammals, acute pneumonia and aspiration pneumonia in neonatal mammals, and upper and lower respiratory tract disease associated with *Proteus mirabillis*, *Pseudomonas aeruginosa*, *Aeromonas* spp. and *Mycoplasma* spp. in reptiles. All resulted in positive outcomes.

To obtain product information, including Material Safety Data Sheet (MSDS) e-mail:info@f10products.com

Manufactured by:
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South Africa
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www.healthandhygiene.co.za

To report a suspected adverse reaction e-mail:info@f10products.com
Adverse reactions may also be reported to the FDA/CVM at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

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F10

f10 antiseptic solution concentrate liquid

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86152-0071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	5.4 g in 100 mL
BIGUANIDE (UNII: FB4Q52I9K2) (BIGUANIDE - UNII:FB4Q52I9K2)	BIGUANIDE	0.4 g in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:86152-0071-2	200 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
legally marketed unapproved new animal drugs for minor species	MIF900007	11/16/2011	

Labeler - Health and Hygiene (Pty) Ltd (636762007)

Establishment

Name	Address	ID/FEI	Business Operations
Health and Hygiene (Pty) Ltd		636762007	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Lonza Group AG		480007517	api manufacture

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