

RENACIDIN- citric acid, gluconolactone and magnesium carbonate solution
United-Guardian, Inc.

Renacidin® (Citric Acid, Glucono Delta-Lactone, and Magnesium Carbonate) Irrigation Solution

DESCRIPTION

Renacidin® (Citric Acid, Glucono delta-lactone, and Magnesium Carbonate) is a sterile, non-pyrogenic irrigation solution for use within the lower urinary tract in the dissolution of bladder calculi of the struvite or apatite variety, and prevention of encrustations of urethral catheters and cystostomy tubes.

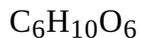
Each 30 mL of Renacidin contains:

Active ingredients:

Citric Acid (anhydrous), USP 1980.6 mg



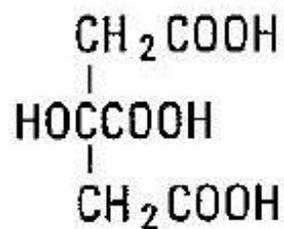
Glucono delta-lactone, USP 59.4 mg



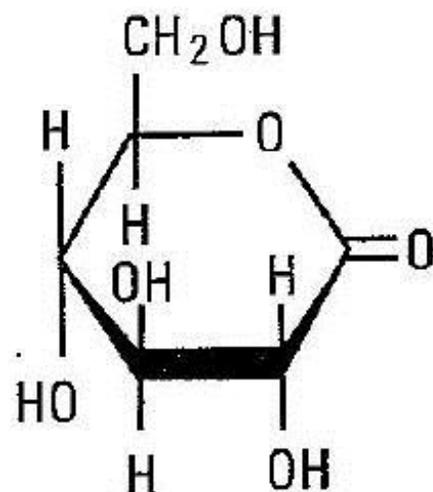
Magnesium Carbonate, USP 980.4 mg



Citric Acid



Glucono delta-lactone



Magnesium Carbonate



Inert ingredients:

Benzoic Acid, USP 6.9 mg
Solution pH: 3.85 (3.5-4.2)

CLINICAL PHARMACOLOGY

Renacidin's action on susceptible apatite calculi results from an exchange of magnesium from the irrigating solution for calcium contained in the stone matrix. The magnesium salts thereby formed are soluble in the gluconocitrate irrigating solution resulting in the dissolution of the calculus. Struvite calculi are composed mainly of magnesium ammonium phosphates which are solubilized by Renacidin due to its acidic pH. Renacidin is not effective for dissolution of calcium oxalate, uric acid or cysteine stones.

INDICATIONS AND USAGE

Renacidin is indicated for dissolution of bladder calculi of the struvite or apatite variety by local intermittent irrigation through a urethral catheter or cystostomy tube as an alternative or adjunct to surgical procedures.

Renacidin is also indicated for use as an intermittent irrigating solution to prevent encrustations of indwelling urethral catheters and cystostomy tubes.

CONTRAINDICATIONS

Renacidin is contraindicated in the presence of demonstrable urinary tract extravasation.

WARNINGS

Renacidin use should be stopped immediately if the patient develops fever, urinary tract infection, signs and symptoms consistent with urinary tract infection, or persistent flank pain. Irrigation should be stopped if elevated serum creatinine develops.

The contents of individual Renacidin containers should not be combined for use as continuous irrigation of the urinary tract because of complications that may arise from inadequate aseptic technique. Terminal sterilization processes that are not adequate may result in sepsis and/or injury to product handlers (e.g., irritation to exposed, unprotected areas of the skin).

Serious adverse reactions, including sepsis and hypermagnesemia, have been reported to occur when Renacidin was used for continuous irrigation of the upper urinary tract. Renacidin is not indicated for continuous irrigation of the upper urinary tract.

PRECAUTIONS

Maintain Patency of the Urethral Catheter or Cystostomy Tube

Care must be taken during therapy with Renacidin to maintain the patency of the urethral catheter or cystostomy tube. Calculus fragments and debris may obstruct the catheter. Catheter outflow blockage may be prevented by flushing the catheter with saline and repositioning of the catheter. Frequent monitoring of the system should be performed by a nurse, an aide or any person with sufficient skills to be able to detect any problems with the patency of the catheter. At the first sign of obstruction, Renacidin should be discontinued.

Caution in Patients with Vesicoureteral Reflux

Patients with an indwelling urethral catheter or a cystostomy tube may have undiagnosed vesicoureteral reflux. Appropriate evaluation prior to initiation of Renacidin is recommended. If reflux is

demonstrated, the potential benefits of therapy should outweigh the risks, and all recommended safety monitoring precautions should be strictly implemented.

Safety Monitoring While on Therapy with Renacidin

Patients should be monitored throughout the course of therapy with Renacidin. Serum creatinine, phosphate and magnesium should be obtained every several days. Urine specimens should be collected for culture and antibacterial sensitivity approximately every three days and at the first sign of fever. Therapy with Renacidin should be stopped if any culture exhibits growth and appropriate antibacterial therapy should be initiated. Therapy with Renacidin may be started again after a course of antibacterial therapy upon demonstration of sterile urine. Struvite calculi frequently contain bacteria within the stone and antibacterial therapy should therefore be continued throughout the course of dissolution therapy. An elevated serum creatinine concentration is also an indication to stop therapy with Renacidin.

Concomitant Use with Medications Containing Magnesium

Concomitant use of Renacidin and medications containing magnesium may contribute to hypermagnesemia in susceptible individuals, such as patients with vesicoureteral reflux. Renacidin Irrigation should be used with caution in patients taking concomitant medications containing magnesium.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term studies to evaluate carcinogenic potential of Renacidin in animals have not been conducted. Mutagenicity studies have not been conducted.

Pregnancy Category C

Animal reproduction studies have not been conducted with Renacidin. It is also not known whether Renacidin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Renacidin should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Magnesium is known to be excreted into human milk. It is not known whether Renacidin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Renacidin is administered to a nursing woman.

ADVERSE REACTIONS

The most common adverse reactions with use of Renacidin for dissolution of bladder calculi or prevention of encrustations of indwelling urethral catheters are “bladder irritability” and chemical cystitis, both reported to occur in approximately 3% of patients. A transient burning sensation in the bladder following Renacidin has been reported to occur in less than 1% of patients receiving Renacidin.

DOSAGE AND ADMINISTRATION

Renacidin for local irrigation within the lower urinary tract is available in single-use 30 mL containers.

Prepare and Administer the Dose:

Step 1: Inspect Renacidin visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration are observed, do not administer.

Step 2: Remove the plastic tab connected to the conical tip of the Renacidin container by twisting the plastic tab. See Figure 1.

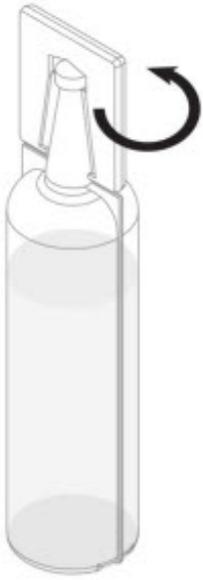


Figure 1

Step 3: Connect the conical tip of the Renacidin container to the end of the urethral catheter or cystostomy tube. See Figure 2.

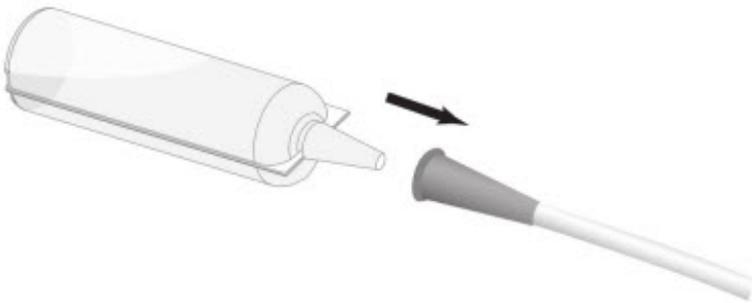


Figure 2

Step 4: Squeeze the Renacidin container to expel the entire contents into the urethral catheter or cystostomy tube. See Figure 3.

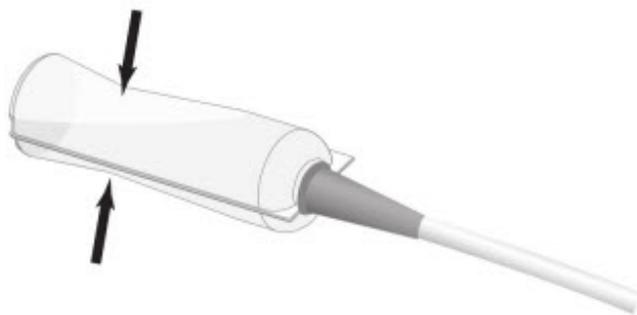


Figure 3

For Dissolution of Bladder Calculi: Instill 30 mL (one container) of Renacidin into the bladder via a urethral catheter or cystostomy tube. Clamp the urethral catheter or cystostomy tube for 30 to 60 minutes. Release the clamp and drain the bladder. Repeat the instillation procedure 4 to 6 times a day. Monitor for dissolution of calculi.

For Prevention of Encrustations in Urethral Catheters and Cystostomy Tubes: Instill 30 mL (one container) of Renacidin into the urethral catheter or cystostomy tube. Clamp the urethral catheter or cystostomy tube for 10 minutes. Remove the clamp and drain the bladder. Repeat the instillation procedure 3 times a day.

HOW SUPPLIED

Renacidin is available as a sterile, non-pyrogenic irrigation solution in 30 mL single-use, low density, polyethylene containers, supplied in boxes of 30 containers each. Exposure of Renacidin to heat or cold should be minimized. Renacidin should be stored at room temperature, 59° to 86°F (15° to 30°C). Avoid excessive heat or cold (keep from freezing). Brief exposure to temperatures of up to 40°C or temperatures down to 5°C does not adversely affect the product.

NDC: 0327-0012-30

PRODUCT CODE: RN030

Revised: November, 2015



Manufactured for
GUARDIAN LABORATORIES
A DIVISION OF
UNITED-GUARDIAN, INC.
Hauppauge, N.Y. 11788
by SMITHS MEDICAL ASD, Vernon Hills, IL 60061



69RN030

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 0327-0012-30

Rx Only

RENACIDIN®

(Citric acid, Glucono delta-lactone,
and Magnesium Carbonate) Irrigation Solution
For Urological Irrigation Only

Each 30 ml. contains:

Active ingredients: Citric acid, anhydrous, USP 1,980.6 mg.;
Glucono delta-lactone, USP 59.4 mg.; Magnesium carbonate,
USP, 980.4 mg. Inert ingredient: Benzoic acid, USP,
6.9 mg. Solution pH: 3.85 (3.5 - 4.2)

Read accompanying package insert for complete instructions on use.
Store at room temperature (59-86°F) (15-30° C). Use only if container
seal is intact, there is no leakage evident and solution is clear.

Box of thirty units – 30 ml. each
Single Dose – Sterile, Non-pyrogenic
Product code: RN030

Made in U.S.A.

Carton Label



RENACIDIN®

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and Magnesium Carbonate) Irrigation Solution
For Urological Irrigation Only



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a division of United-Guardian, Inc., Hauppauge, NY 11788
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Rev. 2 –Nov 2015

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RENACIDIN

citric acid, gluconolactone and magnesium carbonate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0327-0012
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	6.602 g in 100 mL
GLUCONOLACTONE (UNII: WQ29KQ9POT) (GLUCONOLACTONE - UNII:WQ29KQ9POT)	GLUCONOLACTONE	0.198 g in 100 mL
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	3.268 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0327-0012-30	30 in 1 CARTON	02/01/2016	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019481	02/01/2016	

Labeler - United-Guardian, Inc. (050594555)**Establishment**

Name	Address	ID/FEI	Business Operations
United-Guardian, Inc.		050594555	MANUFACTURE(0327-0012)