

**USER INFORMATION
READ CAREFULLY**

RinsA CG 0.1

(CHLORHEXIDINE GLUCONATE 0.1% w/v IRRIGATION SOLUTION)
Sterile Topical Antiseptic Solution

Product Description :

RinsA CG 0.1 is a clear, blue and sterile irrigation solution.

Pharmacodynamics :

Chlorhexidine is an antiseptic and disinfectant which is effective against a wide range of vegetative Gram-positive and Gram-negative organisms, some viruses and some fungi. It is ineffective against bacterial spores at room temperature, and acid-fast bacteria are inhibited but not killed. It is more active against Gram-positive than Gram-negative bacteria and some species of *Pseudomonas* and *Proteus* are relatively less susceptible. Chlorhexidine is most active at a neutral or slightly acid pH and its activity may be reduced by blood and other organic matter.

Pharmacokinetics :

Chlorhexidine is poorly absorbed from the gastrointestinal tract and skin.

Indication :

RinsA CG 0.1 is used for skin and wound irrigation or dressing to prevent and control infection. RinsA CG 0.1 is recommended for use in obstetrics and for swabbing burns and wounds.

Recommended Dosage :

Rinse the area to be cleaned with water, apply the minimum amount of RinsA CG 0.1 necessary to cover the wound area and wash gently. Rinse again thoroughly. Apply to wound as necessary. Discard remaining solution after use.

Route of Administration :

Topical

Contraindications :

RinsA CG 0.1 should not be used in patients with known hypersensitivity to chlorhexidine. It should not be used to irrigate the brain, meninges, eyes or perforated eardrums. RinsA CG 0.1 also should not be used in body cavities or as enema.

Warnings and Precautions :

For external use only. RinsA CG 0.1 is not intended for injection and for irrigation only. It is not isotonic and is haemolytic. RinsA CG 0.1 should not be used as a pre-operative skin preparation for face or head.

Paediatric Use

Use with care in neonates, particularly in premature infants. Chlorhexidine may cause irritation or chemical burns.

RinsA CG 0.1 contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is unknown, but available literature suggests this is likely to be very rare. RinsA CG 0.1 should not be administered to anyone with a possible history of an allergic reaction to chlorhexidine.

If any signs of symptoms of a suspected hypersensitivity reaction such as itching, skin rash, redness, swelling, breathing difficulties, light headedness, and rapid heart rate develop, immediately stop using the product. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Interactions with Other Medicaments:

Chlorhexidine salts are incompatible with soaps and other anionic materials.

Statement On Usage During Pregnancy and Lactation:

Use in Pregnancy - Category A

Chlorhexidine has been used by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Based on negligible topical absorption and a complete lack of any unusual reported effects when used during pregnancy, chlorhexidine would not appear to present a risk to pregnant women. No special precautions or changes in methods of application or use of chlorhexidine seem needed in pregnant health care workers or patients.

Adverse Effects/Undesirable Effects:

Irritative skin reactions and hypersensitivity reactions to chlorhexidine have been reported. In the event that these reactions occur, discontinue use.

Chlorhexidine may cause anaphylaxis.

There have been cases of irreversible corneal damage due to contact with chlorhexidine. Chlorhexidine has been reported to cause deafness when instilled into the middle ear through a perforated eardrum.

Immune system disorders

Frequently not known: Hypersensitivity including anaphylactic shock.

Overdose and Treatment:**In case of accidental or deliberate oral poisoning or ingestion**

Chlorhexidine taken orally is poorly absorbed. Immediate dilution with (120 - 240mL) water or milk (not to exceed 15mL/kg in children) is recommended. The administration of charcoal is not likely to be beneficial and may obscure visualisation during endoscopy. It is not recommended unless other substances known to be absorbed to charcoal are co-ingested. Employ supportive measures as appropriate.

In case of accidental intravenous administration

Haemolysis due to hypotonicity has been reported. Blood transfusion may be necessary to counteract haemolysis.

Storage Condition:

Do not store above 30°C. Protect from light.

Shelf Life:

2 years from manufacturing date in the proposed storage condition.
Do not use after expiry.

Dosage Form and Packaging Available:

30 mL x 20 LDPE Ampoules per box

Manufacturer/Product Registration Holder:

AIN MEDICARE SDN. BHD.

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