Professional Information

SCHEDULING STATUS:

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1. NAME OF THE MEDICINE

D-Germ (chlorhexidine gluconate 0,5 %, n-propyl alcohol 70 %) (Liquid)

2. QUALITATIVE AND QUANTITIVE COMPOSITION:

Each 100 ml of D-Germ contains:

0,5 g chlorhexidine gluconate

70 ml n-propyl alcohol

Other ingredients: polyethylene glycol (PEG6000), rose oil and purified water.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Clear colourless liquid.

4. CLINICAL PARTICULARS:

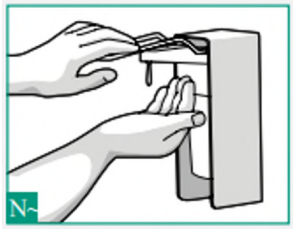
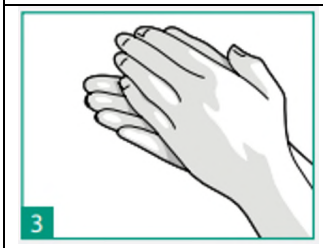
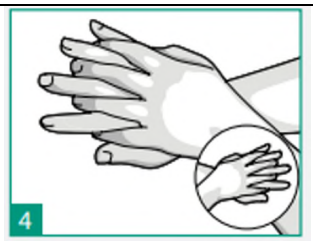
4.1 Therapeutic indications:

The disinfection of the surgeon's hand prior to operative procedure and general hand disinfection. D-Germ has bactericidal, virucidal and fungicidal efficacy.

4.2 Posology and method of administration:

For hygienic hand disinfection, apply palmful of D-Germ on visibly clean hands, covering all surfaces, including fingertips and rub hands well until dry. For surgical hand disinfection, use enough D-Germ to cover all aspects of the hands and forearms, following the correct steps for a minimum of 2 minutes. Repeat process 2 times.

Hand disinfection:

<table>
<tr>
<td colspan="2">
1. Apply a palmful of the product in a cupped hand, enough to cover all hand surfaces.</td>
<td>
2. Rotational rubbing, backwards and forwards with casped fingers of right hand in left palm and vice versa.</td>
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<td>
3. Rub hands palm to palm.</td>
<td>
4. Right palm over left dorsum with interlaced fingers and vice versa.</td>
<td>
5. Palm to palm with fingers interlaced.</td>
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<tr>
<td>
6. Back of fingers to opposing palms with fingers interlocked.</td>
<td>
7. Rotational rubbing of left thumb clasped in right palm and vice versa.</td>
<td>
8. Once dry, your hands are safe.</td>
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Surgical disinfection:

 1. Put approx. 5 ml (3 doses) of alcohol-based handrub in the palm of your left hand.	 2. Dip the fingertips of your right hand in the handrub to decontaminate the nails (5 sec.)	 3. Images 3 – 7: Smear the handrub on the right forearm up to the elbow. Ensure that the whole skin area is covered by using circular movements around the forearm until the handrub has fully evaporated (10 – 15 sec).
		
	 8. Put approx. 5 ml (3 doses) of alcohol-based handrub in the palm of your right hand, using the elbow of your other arm to operate the dispenser.	 9. Dip the fingertips of your left hand in the handrub to decontaminate under the nails (5 sec.).

 10. Smear the handrub on the left forearm up to the elbow. Ensure that the whole skin area is covered by husing circular movements around the forearm until the handrub has fully evaporated (10 – 15 sec.).	 11. Put approx. (3 dose) of alchol-based handrub in the palm of your left hand. Rub both hands at the same time up to the wrists and ensure that all the steps represented in images 12 – 17 are followed (20 – 30 sec.).	 12. Cover the whole surface of the hands up to the wrist with alcohol-based handrub, rubbing palm against palm with a rotating movement.
 13. Rub the back of the left hand, including the wrist, moving the right palm back and forth and vice versa.	 14. Rub palms against palm, back and forth with fingers interlocked.	 15. Rub the back of the fingers holding them in the palm of the other hand with a sideways back and forth movement.
 16. Rub the thumb of the left hand by rotating it in the	 17. When the hands are dry, sterile surgical clothing and gloves can be donned.	Ensure enough product is used. Repeat process 2 times. Duration 2 minutes.

clasped palm of the right hand and vice versa.		

4.3 Contraindications:

Hypersensitivity to Chlorhexidine or to any of the ingredients of D-Germ

Skin sensitivity to Chlorhexidine.

4.4 Special warnings and precautions for use:

For external use only. Not to be taken orally

Avoid contact with eyes. May cause irritation of the conjunctiva and other sensitive tissues (see Undesirable effects).

Avoid contamination of food with this product.

Flammable liquid or vapours – do not keep close to open flame or direct sunlight (see special precautions for storage).

May cause skin irritation

May cause ototoxicity. Contact with middle ear should be avoided

4.5 Interaction with other medicines and other forms of interaction:

D-Germ is incompatible with soap and other anionic agents.

4.6 Fertility, pregnancy and lactation:

Not applicable.

4.7 Effects on ability to drive and use machines:

Not applicable.

4.8 Undesirable effects:

Skin sensitivity to Chlorhexidine and ototoxicity have been reported.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: https://primaryreporting.who-umc.org/ZA

4.9 Overdose:

See “4.8 Undesirable effects”.

Toxic effects due to ingestion of Chlorhexidine should be symptomatic and supportive

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Category A.13.1 Antiseptics, Disinfectants and Cleaning Agents.

Chlorhexidine gluconate is a biguanide with antiseptic activity. It I effective against both Gram-positive and Gram-negative bacteria.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients:

Polyethylene glycol (PEG6000);

Rose oil and

Purified water.

6.2 Incompatibilities:

Do not mix this product with other substances.

6.3 Shelf life:

24 months at 25 ˚C.

6.4 Special precautions for storage:

Store in airtight containers in a cool place, at or below 25 ˚C.

Protect from light and heat.

Keep away from open flames.

Cork closures must not be used.

6.5 Nature and contents of container

100 ml high-density polyethylene (HDPE) plastic container with a mist sprayer cap.

500 ml high-density polyethylene (HDPE) plastic container with a long nose lotion pump or cap.

5 L high-density polyethylene (HDPE) plastic container with a high-density polyethylene cap.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

B. Braun Medical (PTY) LTD

253 Aintree Avenue

Hoogland Ext 41.

Northriding

Randburg, 2194

8. REGISTRATION NUMBER:

Q/13.1/326

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

Registration date:

30 September 1983

10. DATE OF REVISION OF THE TEXT:

Date of last revision:

01 August 2023