SCHEDULING STATUS:

S0

PATIENT INFORMATION LEAFLET

D-GERM, liquid

chlorhexidine gluconate 0,5 %, n-propyl alcohol 70 %

Read all of this leaflet carefully because it contains important information for you:

D-GERM is available without a doctor's prescription. Nevertheless, you still need to use D-GERM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet:

1. What D-GERM is and what it is used for
2. What you need to know before you use D-GERM
3. How to use D-GERM
4. Possible side effects
5. How to store D-GERM
6. Contents of the pack and other information

1. What D-GERM is and what it is used for:

D-GERM is a disinfectant for the disinfection of the surgeon's hands prior to operative procedures and general hand disinfection.

D-Germ is effective against bacteria, viruses and fungus.

2. What you need to know before you use D-GERM:

Do not use D-Germ:

If you are hypersensitive (allergic) to Chlorhexidine or any other ingredients of D-Germ (listed in section 6)

Warnings and precautions:

Special care should be taken with D-Germ as:

It is for external use only.

Not to be taken orally.

It may cause irritation of the conjunctiva and other sensitive tissues (see 4. Possible Effects), therefore eye contact should be avoided.

Avoid contamination of food with this product.

It is a flammable liquid or vapours – do not keep close to open flame or direct sunlight (see 5. How to store D-Germ).

Skin irritation may occur.

It may be toxic to the ear (ototoxicity).

Other medicines and D-GERM:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

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

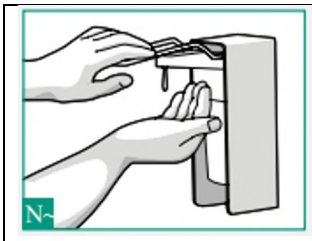
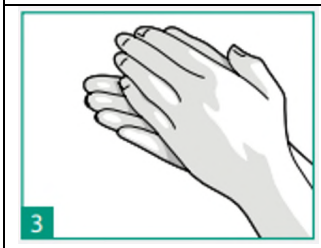
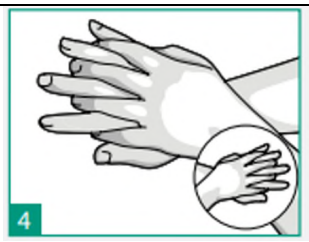
3. How to use D-GERM:

Use D-GERM exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

For hygienic hand disinfection, apply palmful of D-Germ on visibly clean hands 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.

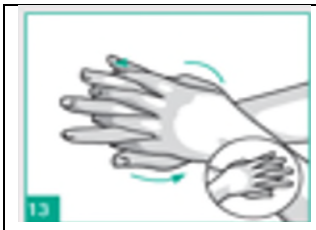
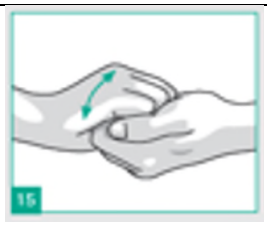
Hand disinfection:

<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>
</tr>
<tr>
<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>
</tr>
<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>
</tr>
</table>

Surgical disinfection:

<table>
<tr>
<td>
1. Put approx. 5 mL (3 doses) of alcohol-based</td>
<td>
2. Dip the fingertips of your right hand in the handrub to</td>
<td>
3. Images 3 – 7: Smear the handrub on the right forearm up to the elbow.</td>
</tr>
</table>

handrub in the palm of your left hand.	decontaminate the nails (5 sec.)	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 clasped palm of the right hand and vice versa.	 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.

If you swallow D-GERM:

See 4. Possible side effects.

In the even that D-Germ is swallowed, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre

4. Possible side effects:

D-GERM can have side effects.

Not all side effects reported for D-GERM are included in this leaflet. Should your general health worsens or if you experience any untoward effects while using D-GERM, please consult your health care provide for advice.

Skin sensitivity to chlorhexidine has been reported. Skin irritation due to chlorhexidine allergy may occur.

Ototoxicity (toxic to the ear) has been reported. D-Germ should not come into contact with the middle ear as this may lead to damage to your inner ear.

If you notice any side effects not mentioned in this leaflet, please inform your doctor of pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://primaryreporting.who-umc.org/ZA.

By reporting side effects, you can help provide more information on the safety of D-GERM.

5. How to store D-GERM:

Store all medicines out of reach of children.

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.

Do not use after the expiry date stated on the bottle.

6. Contents of the pack and other information:

What D-GERM contains:

- The active substance is chlorhexidine gluconate and n-propyl alcohol.
- The other ingredients are polyethylene glycol (PEG6000), rose oil and purified water.

What D-GERM looks like and contents of the pack:

A clear colourless liquid packed in:

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.

Holder of Certificate of Registration:

B. Braun Medical (Pty) Ltd

253 Aintree Avenue

Hoogland Ext 41.

Northriding

Randburg, 2194

Tel nr +27 (0) 222 3000

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The SAHPRA approved professional information can be accessed through:

https://pi-pil-repository.sahpra.org.za/