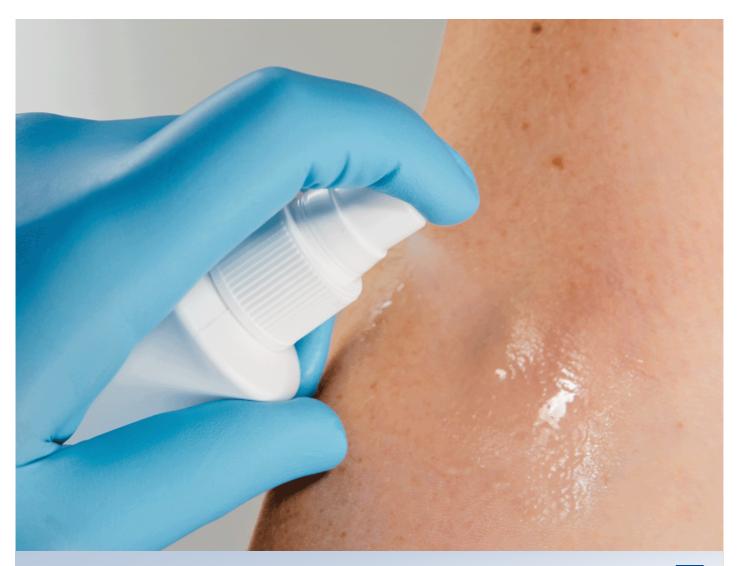


Cutasept_® F Cutasept_® G

Skin antiseptics for use before injections, punctures and surgical procedures with fast and comprehensive activity.



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Cutasept_® F



Product properties

- acts rapidly and comprehensively
- good sustained effect
- excellent skin compatibility
- good adhesion of incision foils

Composition

Active ingredients in 100 g: Propan-2-ol 63.0 g (equals 72 vol. %), Benzalkonium Chloride 0.025 g. Other ingredients: Purified Water.

Microbiology

- bactericidal
- yeasticidal
- tuberculocidal
- virucidal against enveloped viruses

Areas of application

Cutasept F is recommended for the following application areas:

- skin antisepsis prior to injections, punctures and surgical procedures in hospitals, primary healthcare, in- and outpatient geriatric care, and for home dialysis
- diabetics within the scope of measuring the blood sugar level and insulin delivery

Directions for use

Cutasept F is an uncoloured, propanolbased skin antiseptic having a rapid and broad effect. The ready-to-use preparation is used for the preoperative skin antisepsis as well as before blood samplings and injections.

Skin antisepsis before injections, punctures, excisions:

Cutasept F can be sprayed directly on the skin to be disinfected. During spraying keep distance between nozzle and target as short as possible, in order to avoid spray shadows and ensure satisfactory moistening. At the same time, less product gets into the air.

Alternatively, spray the preparation on a sterile swab. Afterwards, rub the skin area to be disinfected with the swab. Pay attention to a thorough wetting of the skin. For both application methods the exposure times, which depend on the respective indication, have to be followed.

<u>Skin antisepsis prior to the application of incision foils:</u>

Cutasept F features especially good adhesion properties for incision foils. In order not to impair the adhesion effect the product has to dry completely before the foil is applied.

Skin antisepsis before thermocautery and the use of other electrical devices:

Before using thermocauters and other electrical devices the product has to dry completely.

Proven efficacy

Exposure time/	
Skin antisepsis	
·	
Before injections and punctures	15 s
•	10.5
Before punctures of joints, visceral cavities,	
hollow organs, and surgical	
procedures.	1 min
Skin rich in sebaceous	1 111111
glandsprior to every	
procedure	2 min
Bacteria	2 111111
Bactericidal acc. to DGHM	
(P. aeruginosa, S.aureus,	
E.hirae, E.coli, P. mirabilis)	15 s
MRSA/ EHEC	1 min
Mycobacteria	
Tuberculocidal (M. terrae)	30 s
Fungi	
Yeasticidal (C. albicans)	15 s
Viruses	
Enveloped viruses	
Virucidal against	
enveloped viruses	30 s
(incl. HCV, HIV, HBV)	
Nonenveloped viruses	
Rotavirus	30 s

Note

- consult a doctor prior to use in neonates and infants
- not suitable for the disinfection of large, open wounds and mucous membranes
- do not use on skin beneath tourniquet cuffs
- ■avoid pooling
- avoid contact with eyes

Chemical-physical data

Appearance uncoloured solution

Density (20 °C) approx. 0.87 g/cm³

■ pH value 50 % (v/v) approx. 8.5

Flash point

(acc. to DIN 51755) 21 °C

Stability

after opening: 12 months

Cutasept_® G



Product properties

- acts rapidly and comprehensively
- good sustained effect
- coloured for marking the disinfection area
- excellent skin compatibility
- good adhesion of incision foils

Composition

Active ingredients in 100 g: Propan-2-ol 63.0 g (equals 72 vol. %), Benzalkonium Chloride 0.025 g. Other ingredients: Purified Water. Dyes: Sunset Yellow S (E110), Quinoline Yellow (E104), Brilliant Black (E151).

Microbiology

- bactericidal
- yeasticidal
- tuberculocidal
- virucidal against enveloped viruses

Areas of application

Cutasept G is recommended for the following application areas:

- skin antisepsis prior to injections, punctures and surgical procedures in hospitals, primary healthcare, in- and outpatient geriatric care, and for home dialysis
- preoperative skin preparation with marking of the disinfection area
- postoperative treatment of skin sutures and adjoining areas

Directions for use

Cutasept G is a coloured, propanol-based skin antiseptic for the preoperative skin antisepsis that marks the disinfected skin area. In addition, the ready-to-use preparation is used prior to injections, catheterisation, punctures, blood sampling and small invasive procedures. Cutasept G acts rapidly and comprehensively, and possesses an excellent sustained effect.

<u>Skin antisepsis before injections,</u> <u>punctures, excisions:</u>

Cutasept G can be sprayed directly on the skin to be disinfected. During spraying keep distance between nozzle and target as short as possible, in order to avoid spray shadows and ensure satisfactory moistening. At the same time, less product gets into the air. Alternatively, spray the preparation on a sterile swab. Afterwards, rub the skin region to be disinfected with the swab.

Pay attention to a thorough wetting of the skin. For both application methods the exposure times, which depend on the

Preoperative skin preparation with marking of the disinfection area:
Cutasept G is applied to the skin area to be disinfected with a sterile swab.
Cutasept G must dry completely.

respective indication, have to be followed.

<u>Skin antisepsis prior to the application of incision foils:</u>

Cutasept G features especially good adhesion properties for incision foils. In order not to impair the adhesion effect the product has to dry completely before the foil is applied.

Skin antisepsis before thermocautery and use of other electrical devices:

Pefere using thermocauters and other

Before using thermocauters and other electrical devices the product has to dry completely.

Proven efficacy

Exposure time/ Procedure		
Skin antisepsis		
Before injections and punctures	15 s	
Before punctures of joints, visceral cavities, hollow organs, and surgical procedures.	1 min	
Skin rich in sebaceous glandsprior to every procedure	2 min	
Bacteria		
Bactericidal acc. to DGHM (P. aeruginosa, S.aureus, E.hirae, E.coli, P. mirabilis)	15 s	
MRSA/ EHEC	1 min	
Mycobacteria		
Tuberculocidal (M. terrae)	30 s	
Fungi		
Yeasticidal (C. albicans)	15 s	
Viruses		
Enveloped viruses Virucidal against enveloped viruses (incl. HCV, HIV, HBV)	30 s	
Nonenveloped viruses Rotavirus	30 s	

Note

- consult a doctor prior to use in neonates and infants
- not suitable for the disinfection of large, open wounds and mucous membranes
- do not use on skin beneath tourniquet cuffs
- avoid pooling
- avoid contact with eyes

Chemical-physical data

Appearance reddish brown solutionDensity (20 °C) approx.

0.82 g/cm³

■ pH value 50 % (v/v) approx. 8.2

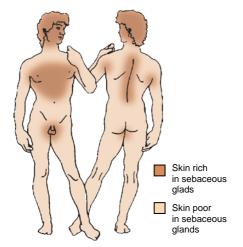
Flash point

(acc. to DIN 51755) 21.5 °C

Stability

after opening:
12 months









Sustained effect

For skin antisepsis, preferably alcoholbased preparations are used. They possess a rapid, broad effect and good skin tolerability. Alcohol-based skin antiseptics obtain an intense initial microorganism reduction. The skin flora then requires a longer time for achieving its baseline bacterial count. With this property - experts define it as sustained effect - alcohol-based antiseptics provide a persistent, antimicrobial effect. During medical procedures, the resident skin flora only recovers very slowly, so that a risk of germ penetration is reduced. As skin antisepsis primarily targets the resident skin flora, the long-term effect plays an important role when selecting a preparation.

Each procedure - from the daily routine injection to extensive surgery penetrates the skin's protective barrier and holds the risk of microorganisms reaching into deeper skin layers. Besides the microorganisms of the transient skin flora, especially the body's resident germs are a potential danger. In case pathogens get into the inside of the body, they can cause abscesses, inflammations and blood stream infections. The danger of infection is significantly reduced by consistent skin antisepsis. For the preand intra-operative infection prophylaxis in operating rooms, the Robert Koch-Institute (RKI) recommends a thorough disinfection of the skin area 1.

¹ Hygiene requirements for surgeries and other invasive procedures. Notification of the Commission of Hospital Hygiene and Infection Prevention at the Robert Koch-Institute, Bundesgesundheitsbl, 2000, 43:644-648

Presentation Cutasept F

50 ml spray bottle, 250 ml spray bottle, 500 ml spray bottle, 1 litre bottle, 5 litre canister.

Presentation Cutasept G

50 ml spray bottle, 250 ml spray bottle, 500 ml spray bottle, 1 litre bottle, 5 litre canister.

Note: The recommendations regarding our preparations are based on scientific tests and are given in good faith. More detailed recommendations, e.g. regarding material compatibility, are possible only in separate, individual cases. Our recommendations are not binding and do not constitute a guarantee. They do not preclude a company's own testing for the intended purpose and process. In this respect we cannot accept any liability. This is in accordance with our general conditions of sale and supply.

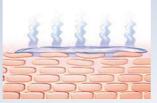
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Sustained activity of skin antiseptics

The skin's own (resident) microorganisms are able to regrow from deeper skin layers and reach the surface. Due to the high initial reduction in microorganisms, alcohol-based skin antiseptics also have a strong effect on resident microorganisms.



Alcohol-based skin antiseptics are very efficient and yield a strong initial reduction in microorganisms on the skin.



After the exposure time, the alcohol evaporates without leaving any residue.

Thus, they retard the growth of the resident flora. Skin antiseptics that have been proven to be effective in practical trials to determine the sustained effect in accordance with the German Society for Hygiene and Microbiology (DGHM) [1] possess sustained activity: even after 24 hours, the initial reduction in resident microorganisms is still almost the same [2, 3].

1 Desinfektionsmittel-Kommission der DGHM: Richtlinie für die Prüfung und Bewertung von Hautdesinfektionsmitteln – Stand 1.1.1991. Zbl Hyg 1991; 192: 99-103.
2 Heeg P. Wirksamkeit von Cutasept F gegen die residente Hautflora.Krankenhaushygieniker.

2 Heeg P. Wirksamkeit von Cutasept F gegen die residente Hautflora.Krankenhaushygieniker Tübingen, 09.08.1992.

3 Christiansen B. Begutachtung von Cutasept G (gefärbt) als Präparat für die Hautdesinfektion. Leiterin der zentralen Einrichtung Medizinaluntersuchungsamt und Krankenhaushygiene Universitätsklinikum Schleswig-Holstein, Campus Kiel, 21.07.2004.

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