BODE

TO WHOM IT MAY CONCERN

We herewith confirm that in principle there is no restriction of use of the skin disinfectants Cutasept® F and Cutasept® G in pediatric units and pediatric surgery. Clinical studies in small children have not been performed. Due to the very limited experience in neonates and infants, the use of Cutasept® F and Cutasept® G in this age group requires a strict indication and supervision by a physician.

It must be taken into consideration that neonate's skin is not a complete barrier to the absorbtion of topically applied agents, particularly damaged, diseased or immature skin. Therefore no antiseptic agent should be applied on neonate's skin without consideration of the effects that might result from percutaneous absorbtion.

Cutasept® F and Cutasept® G are marketed in Germany over 30 years and well known for their good tolerability, mainly in adults. No serious adverse events either in adults or in children have been reported in the literature (MedLine Search 2000 – 2010).

Cutasept® F and Cutasept® G must not be used under blood pressure cuffs and is not suitable for the disinfection of mucous membrane and open wounds and in the area around the eyes. Electrical equipment shall not be used until the skin has dried. Pooling of liquid must generally be avoided.

For further information about the product please refer to the enclosed product information.

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BODE–SCIENCE–COMPETENCE

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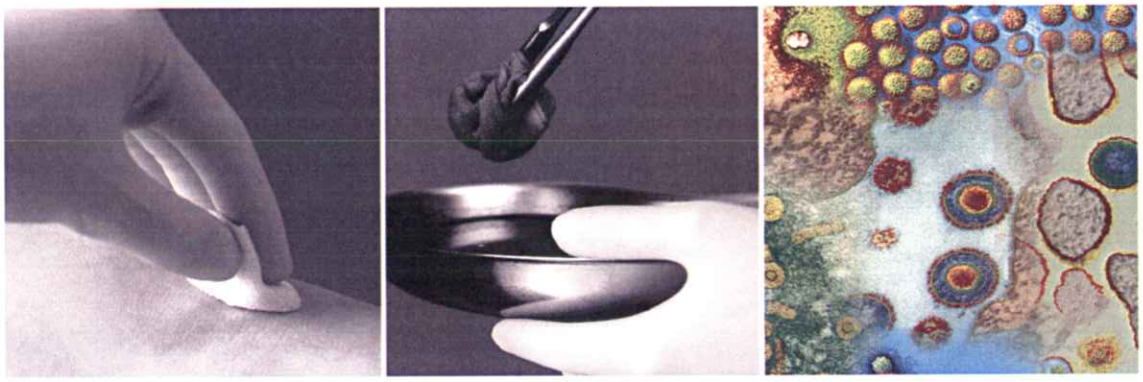
Cutasept® F
Cutasept® G

Skin antisepsis



Skin antiseptics for use before injections, punctures and surgical procedures with fast and comprehensive activity – uncoloured or coloured depending on application area.

A company of the
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HARTMANN

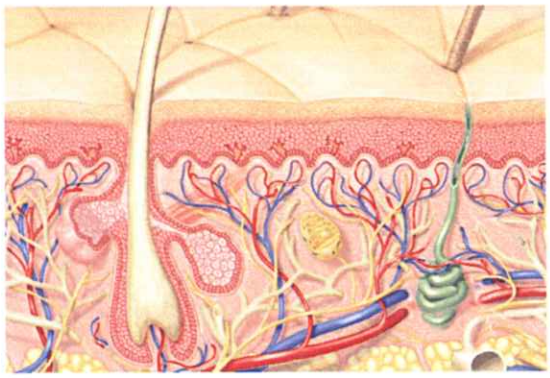
Cutasept® F / Cutasept® G

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 pre- and intra-operative infection prophylaxis in operating rooms, the Robert Koch-Institute (RKI) recommends a thorough disinfection of the skin area [1].

Recommended exposure time

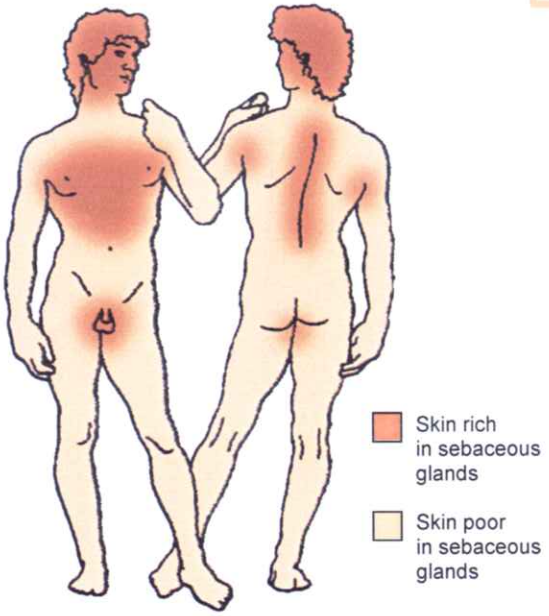
The aim of skin antisepsis is to reduce the entire skin flora as far as possible. Resident skin flora is primarily located in skin regions rich in sebaceous glands and much harder to inactivate than transient skin flora. The more sebaceous glands in the skin, the longer the exposure time has to be in order to achieve a satisfactory reduction of microorganism. This is also what the Robert Koch-Institute recommendation indicates: "As it is much harder to reduce the resident skin flora in skin areas rich in sebaceous glands, longer exposure times are necessary (see manufacturer's instructions)" [1]. Skin antiseptics are categorised as medicinal products and are authorised according to the guideline for the verification and evaluation of skin antiseptics of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM).

The Association for Applied Hygiene (VAH e.V.) summarizes the presently valid exposure times for skin areas rich and poor in sebaceous glands as follows [2]:



[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

[2] Disinfectant list of the Association for Applied Hygiene (VAH e.V.) as of September 1, 2009



Skin poor in sebaceous glands
(e.g. arms, legs, see fig.):

Before injections and punctures	minimum 15 s
Before punctures of joints, visceral cavities and hollow organs, as well as before surgeries	minimum 1 min

Skin rich in sebaceous glands
(e.g. head, chest and upper back, see fig.):

Before every procedure	minimum 1-10 min
10 min with Cutasept® F and Cutasept® G	

The skin has to be constantly kept moist with the antiseptic during the whole exposure time required by the respective indication.

Sustained effect

For skin antisepsis, preferably alcohol-based 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 does not exist. As skin antisepsis primarily targets the resident skin flora, the long-term effect plays an important role when selecting a preparation.

Cutasept® F

Product properties

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

Composition

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

Microbiology

- bactericidal
- yeasticidal
- tuberculocidal
- virucidal against enveloped viruses
- Rotavirus

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
- HIV post-exposition prophylaxis

Directions for use / Dosage

Cutasept® F is an uncoloured, propanol-based 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. Cutasept® F was tested according to DGHM[3] test methods and possesses an excellent sustained effect.

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.

Skin antisepsis prior to the application of incision foils:
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.

[3] Test methods of the German Society for Hygiene- and Microbiology for skin antisepsis as well as for hygienic and surgical hand antisepsis.

Skin antisepsis before thermocautery and the use of other electrical devices:
Before using thermocauters and other electrical devices the product has to dry completely.

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 glands prior to every procedure	10 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)*	
(BVDV, Vacciniavirus)	30 s
Nonenveloped viruses	
Rotavirus	30 s

*acc. to RKI recommendation (Bundesgesundheitsblatt 01-2004)

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

Listing

List of disinfectants of the Association for Applied Hygiene (Verbund für angewandte Hygiene, VAH – former DGHM list)

Chemical-physical data

Appearance	uncoloured solution
Density (20 °C)	approx. 0.87 g/cm^3
pH value 50 % (v/v)	approx. 8.5
Flash point (acc. to DIN 51755)	21 °C

Cutasept® F

Stability

After opening: 12 months

Presentation

50 millilitre spray bottle, 250 millilitre spray bottle,
500 millilitre spray bottle, 1000 millilitre bottle,
5 litre canister.

Possible decanting into smaller containers must be carried out under aseptic conditions (clean bench). Containers used have to be processed appropriately before decanting and comprehensively labelled with clearly legible labels afterwards.

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

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

Microbiology

- bactericidal
- yeasticidal
- tuberculocidal
- virucidal against enveloped viruses
- Rotavirus

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 / Dosage

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

Skin antisepsis before injections, punctures, excisions:
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 respective indication, have to be followed.

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.

Skin antisepsis prior to the application of incision foils:
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:
Before using thermocauters and other electrical devices the product has to dry completely.

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 glands prior to every procedure	10 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)* (BVDV, Vacciniavirus)	30 s
Nonenveloped viruses	
Rotavirus	30 s

*acc. to RKI recommendation (Bundesgesundheitsblatt 01-2004)

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

Listing

List of disinfectants of the Association for Applied Hygiene (Verbund für angewandte Hygiene, VAH – former DGHM list).

Chemical-physical data

Appearance	reddish brown solution
Density (20 °C)	approx. 0.82 g/cm^3
pH value 50 % (v/v)	approx. 8.2
Flash point (acc. to DIN 51755)	21.5 °C

Cutasept® G

Stability

After opening: 12 months

Presentation

50 millilitre spray bottle, 250 millilitre spray bottle,
500 millilitre spray bottle, 1000 millilitre bottle,
5 litre canister.

Possible decanting into smaller containers must be carried out under aseptic conditions (clean bench). Containers used have to be processed appropriately before decanting and comprehensively labelled with clearly legible labels afterwards.

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 only possible in particular cases. Our recommendations are without obligation and do not constitute a warranty. They do not preclude a company's own testing for the intended purposes and processes. In this respect we cannot accept any liability. This complies with our general conditions of sale and supply.

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