

Summary Public Assessment Report

Mediwash (chlorhexidine digluconate)

SE/H/2306/01/DC

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Mediwash
chlorhexidine digluconate

Cutaneous solution, 40 mg/ml

This is a summary of the public assessment report (PAR) for Mediwash. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Mediwash and what is it used for?

The product is a medicine with 'well-established use'. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

How does Mediwash work?

Mediwash contains the active substance chlorhexidine digluconate, which belongs to a group of medicines called antiseptics.

Mediwash is used to disinfect the hands and skin before or after an operation in adults and children, to help prevent infections.

How is Mediwash used?

The pharmaceutical form is cutaneous solution for cutaneous use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

A prescription might be needed for this medicine in Sweden.

What benefits of Mediwash have been shown in studies?

As chlorhexidine digluconate is a well-known substance, and its use in adults and children aged 2 months and older as an antiseptic for pre-operative and post-operative disinfection of the hands and skin is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of chlorhexidine digluconate in the treatment of the above-mentioned indication.

What are the possible side effects from Mediwash?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Mediwash approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Mediwash?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Mediwash

The full PAR for Mediwash can be found on the following website:
<http://mri.medagencies.org/Human/>. For more information about treatment with Mediwash , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-10.