



Impregnated Pad
Chlorhexidine Digluconate / Isopropyl Alcohol

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

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

1 WHAT HEXI PREP IS AND WHAT IT IS USED FOR

HEXI PREP is a single-use impregnated pad containing chlorhexidine digluconate 2% w/v and isopropyl alcohol 70% v/v. The pad contains a fast acting antiseptic solution, which is used by healthcare professionals to disinfect the skin and help prevent infections before invasive medical procedures.

2 WHAT YOU NEED TO KNOW BEFORE YOU USE HEXI PREP

Do not use HEXI PREP

If you are allergic (hypersensitive) to chlorhexidine digluconate or isopropyl alcohol. (See Section 6 'Further information' for a full list of ingredients.)

WARNINGS AND PRECAUTIONS

Talk to your doctor or nurse before using HEXI PREP.

HEXI PREP is for external use only.

HEXI PREP contains chlorhexidine. Chlorhexidine use can result in severe allergic reactions (anaphylactic shock). The prevalence of severe allergic reactions is not known, but available literature suggests this is likely to be very rare. HEXI PREP should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound.

HEXI PREP should not be used:

- Near eyes or delicate linings (mucous membranes), as it may cause irritation. In the case of contact wash immediately with plenty of water.
- On broken skin.
- On the part of the ear that is inside the body (middle ear).
- In direct contact with neural tissue (for example brain and spinal cord tissue).

HEXI PREP should be applied to the skin gently. When the solution has been applied repeatedly or in an over vigorous manner to very fragile or sensitive skin, rash, inflammation, itching, dry and/or flaky skin and pain may occur. At the first sign of any of these reactions, do not continue applications of HEXI PREP.

Avoid prolonged skin contact. Soaked materials, such as drapes or gowns should be removed before use. The solution should not be allowed to pool.

The solution is flammable. Do not use with ignition sources until dry.

HEXI PREP may be used in all age groups and patients.

Children:

However, HEXI PREP should be used with care in newborn babies, especially those born prematurely, as it may cause chemical burns.

Other medicines and HEXI PREP

Tell your doctor or nurse if you have recently had a vaccine or skin test injection (patch test used to test for allergies).

Pregnancy and breast-feeding and fertility

No studies have been undertaken to assess the use of HEXI PREP in pregnant or lactating women.

Pregnancy: No effects during pregnancy are anticipated, since systemic exposure to chlorhexidine digluconate is negligible. HEXI PREP can be used during pregnancy.

Lactation: No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to chlorhexidine digluconate is negligible. HEXI PREP can be used during lactation.

Fertility: The effects of chlorhexidine digluconate on human reproduction have not been studied.

Driving and using machines

HEXI PREP does not affect your driving or ability to use machines.

3 HOW TO USE HEXI PREP

Each individual sachet of HEXI PREP contains a non-woven polyethylene pad soaked in antiseptic solution. Your doctor or nurse will select the correct size of pad based on the procedure site and area to be covered. Your doctor or nurse will rub the pad gently over your skin, covering the intended area of skin. Depending on your medical procedure, more than one pad may be used. HEXI PREP is only used on the skin and each pad is to be used only once. If you have any further questions on the use of this product, ask your doctor or nurse.

4 POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following reactions stop using HEXI PREP and get immediate medical help: swelling of the face, lips, tongue or throat; a red itchy skin rash; wheezing or difficulty breathing; feeling faint and dizzy; a strange metallic taste in the mouth; collapse. You may be having an allergic reaction.

If you develop a rash or your skin becomes itchy, red, dry or inflamed where you have used the product as a skin wash, stop using it and talk to your doctor or pharmacist.

Most commonly, side effects occur within the area of application of the solution and very rarely spread. The most commonly reported reactions include application site rash, redness of the skin (erythema), blistering of the skin, pain at the site of application and itchy skin (pruritus). The frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Very rarely (fewer than 1 in 10,000 people), skin irritation or allergic reactions to the ingredients in HEXI PREP (chlorhexidine digluconate and isopropyl alcohol) have been reported.

Other reactions to the ingredients of HEXI PREP have also been reported at unknown frequency and these include skin reactions (such as dermatitis, eczema, urticaria, and chemical burns in premature babies) and eye disorders (including eye irritation, eye pain, eye redness, impaired vision, chemical burns and eye injury).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse.

This includes any possible side effects not listed in this leaflet.

You can also report the side effects directly via the national reporting system listed below. By reporting side effects, you can help provide more information on the safety of this medicine.

Yellow Card Scheme, Website:

www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the Google Play

or Apple App Store.

5 HOW TO STORE HEXI PREP

Flammable. Do not store above 25 °C.

The pad is sterile unless the seal is broken.

Avoid exposure of the container and contents to naked flames during use, storage and disposal. Do not use after the expiry date stated on the carton.

Keep this medicine out of the sight and reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 CONTENTS OF THE PACK AND OTHER INFORMATION

What HEXI PREP contains

The active substances are chlorhexidine digluconate and isopropyl alcohol. The other ingredient is water.

What HEXI PREP looks like and contents of the pack

Each sachet of HEXI PREP contains a sterile, non-woven pad, soaked in the antiseptic solution.

There are two sizes of pads available:

- 1.5mL containing a 10cm x 10cm pad
- 3mL containing a 20cm x 10cm pad

Marketing Authorisation Holder:



GAMA Healthcare Ltd.,

The Maylands Building,
Maylands Avenue, Hemel Hempstead,
Hertfordshire, HP2 7TG, UK

The Manufacturer of HEXI PREP is:

Naturelle Consumer Products Ltd,
Unit 5 Bankmore Way, East industrial Park,
Doogary, Omagh, Co. Tyrone,
Northern Ireland, BT79 ONZ

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland – HEXI PREP

UK – HEXI PREP

Is this leaflet difficult to read? You can ask for a copy either in large print, Braille, on CD or tape cassette by calling the MA Holder at: +44 20 7993 0030

This leaflet was last revised in March 2021.