Package leaflet: Information for the Patient
Hexiprep 2%w/v / 70%v/v) Impregnated Pad
Chlorhexidine Digluconate 2%w/v / Isopropyl Alcohol 70%v/v

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 Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad is and what it is used for?

Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad 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 Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad.

Do not use Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad
- if you are allergic (hypersensitive) to chlorhexidine digluconate or isopropy alcohol. (See Section 6 'Further information' for a full list of ingredients.)

Warnings and Precautions:
Talk to your doctor or nurse before using Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad.

Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad is for external use only.

Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad 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. Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound.

Avoid contact with the brain, meninges (the membranes surrounding the brain and spinal cord), the middle ear, broken skin or mucous membranes (delicate linings).

Hexiprep 2.0%w/v / 70%v/v Impregnated Pad must not come into contact with the eye due to the risk of visual damage. If it comes into contact with the eyes, wash out immediately and thoroughly with water. In case of any irritation, redness or pain in the eye, or visual disturbance, ask for medical advice promptly.

Serious cases of persistent corneal injury (injury to the surface of the eye) potentially requiring corneal transplant have been reported when similar products have accidentally come in contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).

Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad should be applied to the skin gently. When the solution has been applied repeatedly or in an overvigorous 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 Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad.

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.

Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad may be used in all age groups and patients.

Children:
However, Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad should be used with care in newborn babies, especially those born prematurely, as it may cause chemical burns.

Other medicines and Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad
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 Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad in pregnant or lactating women.

Pregnancy: No effects during pregnancy are anticipated, since systemic exposure to chlorhexidine digluconate is negligible. Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad 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. Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad can be used during lactation.

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

Driving and using machines
Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad does not affect your driving or ability to use machines.

3. How to use Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad

Each individual sachet of Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad contains a non-woven polyethylene pad soaked in antiseptic solution. Your doctor or nurse will select the correct size of impreganted 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. Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad 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 Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad 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 Hexiprep2.0%w/v / 70.0% v/v Impregnated Pad (chlorhexidine digluconate and isopropyl alcohol) have been reported.

Other possible side effects, for which it is not known how often they occur, are:

-Skin disorders such as dermatitis (inflammation of the skin), pruritus (itch), erythema (redness of the skin), eczema, rash, urticaria (hives), skin irritation, blisters and chemical burns in premature babies.

-Eye disorders including eye irritation, eye pain, eye redness, chemical burns, corneal injury (injury to the surface of the eye), and permanent eye damage including permanent visual impairment (following accidental ocular exposure during head, face and neck surgical procedures) in patients under general anaesthesia (deep painless sleep).

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.

HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 3762517
Website: www.hpra.ie
Email: medsafety@hpra.ie

5. How to store Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad

Flammable. Do not store above 25 ºC.

The impreganted 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 Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad contains
The active substances are chlorhexidine digluconate and isopropyl alcohol. The other ingredient is water.

What Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad looks like and contents of the pack

Each sachet of Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad contains a sterile, non-woven pad soaked in the antiseptic solution. There are two sizes of pad available:

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

Marketing Authorisation Holder and Manufacturer
GAMA Healthcare Ireland Ltd,1st Floor, Lapp's Quay, Cork, IRELAND

The Manufacturer of Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad is:

Naturelle 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 – Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad

This medicinal product is also authorised in the UK under the name:

HEXI PREP 2.0%w/v / 70.0% v/v Impregnated Pad

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 +353 1 513 41 38.

This leaflet was last revised in July 2024
<--->

The following information is intended for medical or healthcare professionals only:

Instructions for Using Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad

Posology

Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad may be used on all age groups and patient populations.

Paediatric Population

However, Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad should be used with care in newborn babies, especially those born prematurely.

One sachet is used containing pad impregnated with 1.5mL or 3mL of the Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad alcoholic solution.

Method of Administration

For cutaneous use.

The choice of Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad sachet will depend on the size of the area to be disinfected, the invasive procedure and the clinician's preference.

Sachet Volume / Impregnated Pad Size	**Maximum Coverage Area**	**For procedures such as:**
1.5mL (10 cm x 10cm)	10cm x 13cm	• blood culture collection, • peripheral cannulation, • peripheral arterial line cannulation, • simple biopsy, • routine venepunctures • dialysis / fistula / graft site cleansing.
3.0mL (20cm x 10cm)	15cm x 15cm	• blood culture collection, • peripheral cannulation, • peripheral arterial line cannulation, • midline and central venous catheter (CVC) insertions and maintenance, • simple biopsy, • routine venepunctures, • dialysis fistula / graft site cleansing, peritoneal dialysis site cleansing • implantable device placement

Where required as part of sterile procedure (e.g. central line insertion), tear the sachet open and remove the impregnated pad with sterile tweezers onto a sterile tray. Contact with the outer face of the sachet by sterile gloves should be avoided as it is non-sterile.

For both non-sterile and sterile procedures, the user should wear gloves during application. Keep the impregnated pad folded and press firmly against the skin on the intended area and wipe back and forth, as demonstrated in Diagram 1 for 30 seconds. Allow to airdry completely. It is recommended that the Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad solution remains on the skin post procedure to provide continued antimicrobial activity. If removal is necessary, remove with soap and water or alcohol.

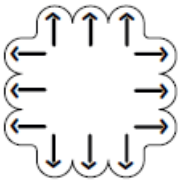

Diagram 1

Precautions for Use

- For external use only
- Allow Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad solution to dry completely before starting any medical procedure. Do not use with electrocautery procedures until dry. Remove any soaked materials, towels, drapes or gowns before proceeding. Do not allow to pool. Where occlusive dressings are to be applied to areas previously exposed to Hexiprep2.0%w/v / 70.0% v/v Impregnated Pad, care must be taken to ensure no excess product is present prior to application of the dressing.
- Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare.
- Avoid contact with the brain, meninges, the middle ear, broken skin or mucous membranes.
- Hexiprep 2.0%w/v / 70%v/v Impregnated Pad must not come into contact with the eye due to the risk of visual damage. If it comes into contact with the eyes, wash out immediately and thoroughly with water. In case of any irritation, redness or pain in the eye, or visual disturbance, ask for medical advice promptly. Serious cases of persistent corneal injury (injury to the surface of the eye) potentially requiring corneal transplant have been reported when similar products have accidentally come in contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).
- Chlorhexidine digluconate is incompatible with soap and other anionic agents.
- Alcohol should not be brought into contact with some vaccines and skin test injection sites (patch tests). If in doubt, consult the vaccine manufacturer's literature.
- Do not apply the solution in an over vigorous manner to very fragile or sensitive skin. After repeated use, local skin reaction may occur including; erythema or inflammation, itching, dry and/or flaky skin and local application site pain. At the first sign of local skin reaction, do not continue application of Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad

Special Precautions for Disposal
The solution is flammable. Do not use near naked flames, strong heat sources or while smoking. Avoid exposure of the container and contents to naked flames during use, storage and disposal. Discard the impreganted pad after use as per clinical waste procedures.

Please refer to the Summary of Product Characteristics for Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad for further detailed information.

Storage Procedures
Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad is for single use only. The impregnated pad is sterile until the packaging is opened. Do not use Hexiprep 2.0%w/v / 70.0% v/v Impregnated Pad after the expiry date stated on the label or carton. The expiry date refers to the last day of that month. Do not store above 25ºC.