Package leaflet: Information for the user

PurPrep 8.3% w/w / 72.5% w/w cutaneous solution in single-dose container

For adults, adolescents, and children 1 year of age or older

iodinated povidone/ isopropyl alcohol

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PurPrep is and what it is used for
2. What you need to know before you use PurPrep
3. How to use PurPrep
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1. What PurPrep is and what it is used for

PurPrep is a sterile cutaneous solution, containing the active substances iodinated povidone, and isopropyl alcohol. The cutaneous solution is available in a plastic applicator with a sponge tip on one end.

PurPrep is an antiseptic used for disinfection of intact skin before invasive medical procedures (including surgery), to help reduce microorganisms (bacteria and yeasts) that can potentially cause infection. PurPrep is indicated in adults, adolescents, and children 1 year of age or older.

2. What you need to know before you use PurPrep

Do not use PurPrep

- If you are allergic to iodinated povidone, and isopropyl alcohol or any of the other ingredients of this medicine (listed in section 6).
- On children less than 1 year of age.
- On patients with dermatitis herpetiformis;
- On patients with hyperthyroidism and other thyroid dysfunction.

Warnings and precautions

Talk to your doctor or nurse before PurPrep is used.

PurPrep is for single and external use on intact skin only.

PurPrep should not be administered to anyone with a potential history of allergy to iodinated povidone compounds.

PurPrep must not be used:

- near eyes or mucous membranes, as it may cause irritation. If it accidentally occurs, it should be washed quickly with plenty of water.
- on open skin wounds or as a general skin cleanser.
- in direct contact with neural tissue and the middle ear

If symptoms of an anaphylactic reaction are detected, application of PurPrep should be stopped immediately.

If the solution has been applied in an over-vigorous manner to very fragile or sensitive skin or after repeated use, application-site reactions such as pruritus, erythema, rash, papules, and vesicles may occur (see section 4). At the first sign of any of these reactions, applications of PurPrep should be stopped.

Prolonged skin contact should be avoided.

Soaked materials, such as drapes or gowns should be removed before use. The solution should not be allowed to pool. Where occlusive dressings are to be applied to areas previously exposed to PurPrep, care must be taken to ensure no excess product is present prior to application of the dressing.

The solution is flammable. When using PurPrep, use in a well-ventilated area. Do not use ignition sources such as cigarettes, naked flames or a strong heat source until the skin is completely dry.

Thyroid disorder and renal insufficiency

PurPrep should be used with caution in patients with thyroid disorder (i.e., hyperthyroidism, mild nodular goitre) and in patients with renal insufficiency due to prolonged time of elimination. Very rare cases of iodine-induced hyperthyroidism have been reported with iodinated povidone containing products.

With repeated application, there may be a potential for increased drug absorption, skin irritation and thyroid disorder (see sections 3 and 4). If re-operation is necessary within a few days following the application of PurPrep, the use of a preoperative antiseptic that does not contain iodinated povidone, or close monitoring of thyroid function, should be determined by the clinician.

Children

PurPrep is contraindicated on children less than 1 year due to an increased iodine absorption that can occur from topical administration of iodinated povidone to immature skin, especially in pre-term infants.

The use of alcohol-based solutions, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates (see section 4).

Other medicines and PurPrep

Tell your doctor or nurse if you are using, have recently used or might use any other medicines, specifically:

- a vaccine or skin test injection (patch test used to test for allergies).
- those that contain proteins such as those in blood which may impair efficacy.
- disinfectants containing mercury due to the risk of chemical burns following the formation of mercury iodide.
- certain antiseptics (octenidine), as dark discolouration can occur at the treated areas.
- those that contain hydrogen peroxide or taurolodine, as oxidation can weaken the activity of the drug.
- those that contain silver-containing disinfectants or wound dressings that can form silver iodine.
- lithium therapy, as rare instances of hypothyroidism have been reported.
- the results of certain thyroid tests may be affected.

Pregnancy, breast-feeding and fertility

PurPrep should be used with caution during pregnancy or breastfeeding, since absorption of iodine into the mother's blood (even through intact skin) and excretion into human breast milk may occur.

During pregnancy and lactation, PurPrep, like all iodine preparations, should only be administered following a very careful assessment of the risk/benefit by the doctor.

Driving and using machines

PurPrep has no or negligible influence on the ability to drive and use machines.

3. How to use PurPrep

The antiseptic solution within the PurPrep system is kept inside the plastic applicator. Your doctor or nurse will select the applicator size based on the procedure site and area to be covered. The medicinal product is for cutaneous use.Your doctor or nurse will rub the sponge over your skin, covering the skin area that needs to be prepared. Depending on your medical procedure, more than one applicator may be used.

PurPrep is only used on the intact skin and each applicator is only used once.

PurPrep is for single use only.

If you have any further questions on the use of this medicinal product, ask your doctor or nurse.

4. Possible side effects

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

A very rare but serious side effect is anaphylaxis (may affect up to 1 in 10,000 people).

If you develop swelling of the face, lips, tongue or throat; wheezing or difficulty breathing; feeling faint and dizzy; a strange metallic taste in the mouth; or collapse, you may be having an anaphylactic reaction. Stop using PurPrep and talk to your doctor, nurse or pharmacist.

Other allergic-type skin and sensitisation reactions have been reported rarely (may affect up to 1 in 1,000 people). If you experience any of the following symptoms, the product application should be stopped immediately: pruritus (itching), erythema, skin rash, papules, vesicles, dry or inflamed skin, and contact dermatitis.

Very rare instances of hyperthyroidism and angiodema may occur (may affect up to 1 in 10,000 people).

The following possible effects have been described with PurPrep after prolonged use, application over large coverage areas or on non-intact skin (frequency cannot be estimated from the available data):

- Chemical and thermal burns, associated with the use of alcohol-based solutions
- Exfoliative dermatitis
- Hypothyroidism in specific patient populations
- Metabolic acidosis
- Electrolyte imbalance
- Renal insufficiency

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store PurPrep

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

Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

PurPrep is flammable. Do not store above 30°C. Avoid exposure of the container and contents to naked flames during use, storage and disposal.

Store in the original packaging; PurPrep is sterile unless the seal is broken.

After opening, the medicinal product should be used immediately.

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 PurPrep contains

- The active substances are iodinated povidone and isopropyl alcohol.
  Each 1 ml solution contains 72.5 mg of iodinated povidone and 633 mg of isopropyl alcohol.

  Each applicator with 10.5 ml solution contains 761 mg of iodinated povidone (72.5 mg/ml) and 6646 mg of isopropyl alcohol (633 mg/ml).
- Each applicator with 26 ml solution contains 1884 mg of iodinated povidone (72.5 mg/ml) and 16456 mg of isopropyl alcohol (633mg/ml). The other ingredients are methacrylic acid-methyl methacrylate copolymer (1:2), acrylates / octylacrylamide copolymer, macrogol 400, 2-amino-2-methyl-1-propanol (95%) and purified water.

What PurPrep looks like and contents of the pack

PurPrep is a cutaneous solution contained in applicators containing either 10.5 ml or 26 ml of solution.

The solution is hermetically sealed within a type I glass ampoule housed in a single-use sterile applicator.

The 10.5 ml applicator contains 1 type I glass ampoule, while the 26 ml contains 2 type I glass ampoules of 13 ml each. When the applicator is activated, the solution is released from the glass ampoule(s) and allowed to flow into the foam on top of the applicator body for cutaneous application.

The packaging consists of a lidding material sealed to a polymeric film creating a “pouchlike" packet surrounding the applicator. The final packaged applicator is sterilised using ethylene oxide.

Pack sizes:

1 applicator containing 10.5 ml cutaneous solution.

25 applicators each containing 10.5 ml cutaneous solution.

1 applicator containing 26 ml cutaneous solution.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
Becton Dickinson UK Limited,
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Customer contact for adverse events or medical information inquiries: 0800 0437 546

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or

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------- The following information is intended for healthcare professionals only:

Instructions for using PurPrep:

- PurPrep may be used on patient populations 1 year of age or older.
- Single use applicator. With repeated application, there may be a potential for increased drug absorption, skin irritation and thyroid disorder.
- PurPrep should only be applied after a careful consideration in elderly patients with thyroid disorder.
- For cutaneous use. For external use only.
- Remove the applicator from the wrapper and hold it with the sponge facing downward.
  - Pinch wings or press lever once only to activate the applicator.
- Do not repeatedly pinch or pump in an attempt to accelerate the saturation of the foam.
- Press the sponge against the patient's skin in order to apply the antiseptic solution.
- Once the solution is visible on the skin, use back and forth strokes to prep the site for 30 seconds.
- Allow the covered area to air dry completely.

PurPrep solution can be left on the skin post procedure.

Maximum coverage areas:

- 10.5 ml: 25 cm x 30 cm
- 26 ml: 50 cm x 50 cm

Precautions for Use:

- Allow PurPrep solution to dry completely before starting any medical procedure. Do not use during electrocautery procedures or with other ignition sources until the skin is completely dry. Do not use while smoking or near any naked flames or strong heat sources.
- Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or to drip on sheets or other material in direct contact with the patient.
- Where occlusive dressings are to be applied to areas previously exposed to PurPrep, care must be taken to ensure no excess product is present prior to application of the dressing.
- Do not use on children less than 1 year of age because of the potential for excessive skin irritation and absorption of iodine. PurPrep may cause chemical burns in neonates.
- Use with caution in women who are breastfeeding due to the potential for transient hypothyroidism in the nursing newborn.
- Do not use near eyes or mucous membranes. If it does get into the eye or the mucous membranes, it should be washed quickly with plenty of water.
- Do not use on open skin wounds or as a general skin cleanser. Do not use on broken or damaged skin and in direct contact with neural tissue or the middle ear.
- Alcohol should not be brought into contact with some vaccines and skin test injections (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, application-site reactions such as pruritus, erythema, rash, papules, and vesicles may occur. At the first sign of local skin reaction, stop application of PurPrep.
- Do not use in patients with known hypersensitivity to PurPrep solution or any of its components, especially in those patients with a history of possible allergic reaction to iodinated povidone compounds.
- If symptoms of an anaphylactic reaction are detected, application of PurPrep should be stopped immediately.
- Use with caution in patients with thyroid disorder (i.e hyperthyroidism, mild nodular goitre) and patients with renal insufficiency due to prolonged time of elimination.
- If re-operation within a few days following application of PurPrep is necessary, the use of a preoperative antiseptic not containing iodinated povidone, or close monitoring of thyroid function is advised.

Treatment of overdose

In case of accidental ingestion of large quantities of product, institute symptomatic and supportive treatment with particular attention to the renal and thyroid function.

Incompatibilities

Iodine, as iodinated povidone, may react with organic matter such as blood proteins. It should not be used with reducing agents, silver, mercury, taurolidine, disinfectants containing silver, octenidine, hydrogen peroxide or in patients receiving concomitant lithium therapy.

Absorption of iodine from iodinated povidone, through either healthy or damaged skin, may interfere with thyroid functions tests. However, there is little absorption of iodine through intact skin.

Special precautions for disposal

The solution is flammable. Do not store above 30°C. Avoid exposure of the container and contents to naked flames during use, storage, and disposal. Discard the applicator after use as per clinical waste procedures.

Please refer to the Summary of Product Characteristics for PurPrep for further detailed information.