

UNIDINE Povidone Iodine Solution 10% w/v

Povidone Iodine (10% w/v)

What is in this leaflet

1. What UNIDINE is used for
2. How UNIDINE works
3. Before you use UNIDINE
4. How to use UNIDINE
5. While you are using UNIDINE
6. Side effects
7. Storage and disposal of UNIDINE
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What UNIDINE is used for

It is indicated as disinfectant and antiseptic for the treatment of contaminated wounds, cuts and burns and also for the pre-operative preparation of the skin and mucous membrane.

How UNIDINE works

UNIDINE contains povidone iodine which is a broad spectrum antiseptic for topical application in the treatment and prevention of wound infection.

Before you use UNIDINE

-When you must not use it

It should not be used if you:

- had known to be hypersensitive to iodine, polyvinylpyrrolidone or to any components of the formulation.
- had history of abnormal thyroid function or goiter (swelling of the neck).
- on concurrent lithium therapy (for depression).

Do not use in children under two years of age.

-Before you start to use it

- Use of this preparation may interfere with tests of thyroid function.
- Caution to individual with kidney insufficiency and impaired kidney function.

Pregnancy and lactation

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breastfeeding.

Iodine freely crosses the placenta and is secreted in breast milk. Therefore it is recommended that breastfeeding should stop during treatment, unless no alternative is possible.

Thyroid function disorders have been reported in the offspring of mothers exposed to pharmacological doses of iodine. Povidone iodine should not be used regularly during pregnancy unless there is no alternative treatment available.

-Taking other medicines

Inform your doctor or pharmacist before taking this medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

- Lithium can interact with UNIDINE to affect the function of the thyroid gland. Therefore, concurrent use should be avoided.
- Absorption of iodine through either intact skin or broken skin may interfere with thyroid function tests.
- Contamination with povidone iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false-positive results.

How to use UNIDINE

-How much to use

Always use UNIDINE as recommended.

The usual dose:

To be used undiluted. Apply directly to skin. Allow to dry before applying dress, drape or cast.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue using UNIDINE as your doctor recommended. If symptoms persist, consult your doctor.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of

this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much UNIDINE may cause:

- goiter (swelling of the neck) and underactive thyroid or overactive thyroid.
- metallic taste in mouth
- increased salivation
- burning or pain in the throat or mouth
- irritation and swelling of the eyes
- fluid accumulation in the lungs
- skin reactions
- gastrointestinal upset and diarrhea
- metabolic acidosis
- high level of sodium in the blood and kidney impairment.
- Deliberate or accidental ingestion of large quantities of povidone iodine will result in high blood levels of iodine and gastrointestinal toxicity including vomiting and diarrhoea.

While you are using UNIDINE

-Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking UNIDINE.

- Things you must not do

- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give UNIDINE to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

For external use only.

Side effects

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

Tell your doctor if you notice any of the following side effects:

- local irritation, skin burns and sensitivity reactions.
- hypersensitive reactions.
- deficient of iodine and underactive thyroid or overactive thyroid.
- metabolic acidosis and acute kidney failure.

UNIDINE Povidone Iodine Solution 10% w/v

Povidone Iodine (10% w/v)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Serial Number

NPRA(R2/2)240430/1264

Storage and disposal of UNIDINE

-Storage

Store below 30°C & Protect from light.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

-What it looks like

A deep brown liquid.

-Ingredients

-Active ingredient

Povidone Iodine (10% w/v)

-Inactive ingredients

Citric Acid Anhydrous, Anhydrous Disodium Hydrogen Phosphate, Glycerine, Potassium Iodide, Potassium Iodate, Hydroxy Propyl Methyl Cellulose E15, Purified Water

-MAL number

MAL18056086XZ

Product Registration Holder:

KCK Pharmaceutical Industries Sdn. Bhd.

Plot 61, Bayan Lepas Industrial Park
Phase 4, Lintang Bayan Lepas 1,
11900 Bayan Lepas,
Pulau Pinang, Malaysia.

Manufactured by:

KCK Pharmaceutical Industries Sdn. Bhd.

No. 5 & 7 Hala Beringin,
Diamond Valley Industrial Park,
11960 Bayan Lepas,
Pulau Pinang, Malaysia.

Date of revision

14/05/2024