

Summary of product characteristics for a biocidal product

Product name: Betadine solution

Product type(s): PT01 - Human hygiene (Disinfectants)

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Authorisation number: HU-2018-PA-01-00228-0000

R4BP 3 asset reference number: HU-0016892-0000

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Administrative information

1.1. Trade names of the product

Betadine solution

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Egis Pharmaceuticals PLC
	Address	Keresztúri út 30-38. 1106 Budapest Hungary
Authorisation number	HU-2018-PA-01-00228-0000	
R4BP 3 asset reference number	HU-0016892-0000	
Date of the authorisation	10/12/2018	
Expiry date of the authorisation	01/12/2028	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Egis Pharmaceuticals PLC.
Address of the manufacturer	Keresztúri út 30-38. H-1106 Budapest Hungary
Location of manufacturing sites	Mátyás Király u. 65. H-9900 Körmend Hungary

1.4. Manufacturer(s) of the active substance(s)

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	Ashland Services BV
Address of the manufacturer	Pesetastraat 5 3009 AP Rotterdam Netherlands
Location of manufacturing sites	455 North Main Street KY 42029 Calvert City United States

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		10
Nonylphenol polyglycol ether			9016-45-9		0,0971

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	<p>Avoid release to the environment.</p> <p>Dispose of contents to in accordance with local and national regulations.</p> <p>Keep out of reach of children.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p>

4. Authorised use(s)

4.1 Use description

Use 1 - Skin disinfection

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Skin disinfection
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Common name: Bacteria, aerobic Gram-positive Development stage: Scientific name: Common name: Fungi Development stage: Scientific name: Common name: Adenovirus Development stage: - Scientific name: Common name: Norovirus Development stage: Scientific name: Common name: Enveloped viruses Development stage: Scientific name: Common name: Mycobacteria Development stage:
Field(s) of use	Indoor The preparation is indicated: <ul style="list-style-type: none">• as a skin disinfectant to be used prior to injection, blood sampling, punctures, biopsy, transfusion, infusion• for disinfection of the skin prior to surgery
Application method(s)	Manual application - The Betadine solution has to be used undiluted for skin disinfection. Exposure time is 1-2 minutes prior to injection, blood sampling or any other puncture, biopsy, transfusion or infusion or any other surgery on intact skin.
Application rate(s) and frequencies	concentrated - 100% - Maximum 10 times per day.
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material

General public (non-professional)

Bottle, HDPE , 30ml in folded cardboard box

Bottle, HDPE , 120ml in folded cardboard box

Bottle, HDPE , 1000ml in folded cardboard box

4.1.1 Use-specific instructions for use

See chapter 5.1.

4.1.2 Use-specific risk mitigation measures

See chapter 5.2.

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See chapter 5.3.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See chapter 5.4.

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4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See chapter 5.5.

4.2 Use description

Use 2 - Disinfection bath

Product type

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Disinfection bath

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria, aerobic Gram-negative
Development stage: -

Scientific name:
Common name: Bacteria, aerobic Gram-positive
Development stage: -

Scientific name:
Common name: Fungi
Development stage: -

Scientific name:
Common name: Mycobacteria
Development stage: -

Field(s) of use

Indoor

The preparation is indicated:

- for total or partial pre-surgery disinfection of the patient (disinfection bath)

Application method(s)

Manual application -

The Betadine solution can be taken diluted in water as 1% (1:100) for bath disinfection. The 1% solution of Betadine has bactericide, fungicide and mycobactericide effects.

For the pre-surgery disinfection bath a 1% solution (1:100) is used. The whole body surface should be cleaned evenly with a 1% solution of Betadine and after a 2-min exposure washed with warm water.

The diluted solution should be prepared immediately prior to application and should not be stored.

Betadine solution stains can be removed clothes by washing in hot water; if the stain is severe use a solution of sodium thiosulfate.

Application rate(s) and frequencies

diluted - 1% -
Maximum 10 times per day.

Category(ies) of users

Trained professional
Professional
General public (non-professional)

Pack sizes and packaging material

Bottle, HDPE , 30ml in folded cardboard box

Bottle, HDPE , 120ml in folded cardboard box

Bottle, HDPE , 1000ml

4.2.1 Use-specific instructions for use

See chapter 5.1.

4.2.2 Use-specific risk mitigation measures

See chapter 5.2.

4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See chapter 5.3.

4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See chapter 5.4.

4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See chapter 5.5.

4.3 Use description

Use 3 - Hygienic hand disinfection

Product type

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Hygienic hand disinfection

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria, aerobic Gram-negative
Development stage:

Scientific name:
Common name: Bacteria, aerobic Gram-positive
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Scientific name:
Common name: Adenovirus
Development stage: -

Scientific name:
Common name: Norovirus
Development stage:

Scientific name:
Common name: Enveloped viruses
Development stage:

Scientific name:
Common name: Mycobacteria
Development stage:

Field(s) of use

Indoor

The preparation is indicated:

- as a hygienic hand disinfectant.

Application method(s)	Manual application - The Betadine solution has to be used undiluted for hygienic hand disinfection with a 1 minute exposure time.
Application rate(s) and frequencies	concentrated - 100% - Maximum 10 times per day.
Category(ies) of users	Trained professional Professional General public (non-professional)
Pack sizes and packaging material	Bottle, HDPE , 30ml in folded cardboard box Bottle, HDPE , 120ml in folded cardboard box Bottle, HDPE , 1000 ml

4.3.1 Use-specific instructions for use

See chapter 5.1.

4.3.2 Use-specific risk mitigation measures

See chapter 5.2.

4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See chapter 5.3.

4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See chapter 5.4.

4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See chapter 5.5.

5. General directions for use

5.1. Instructions for use

The Betadine solution can be taken undiluted or diluted in water as 1% (1:100), depending to the region we want to disinfect. Exposure time is 1-2 minutes undiluted prior to injection, blood sampling or any other puncture, biopsy, transfusion or infusion or any other surgery on intact skin.

For hygienic hand disinfection undiluted, exposure is 1 minute.

For the pre-surgery disinfection bath a 1% solution (1:100) is used. The whole body surface should be cleaned evenly with a 1% solution of Betadine and after a 2-min exposure washed with warm water.

The 1% solution of Betadine has bactericide, fungicide and mycobactericide effect.

In pre-operative preparation, avoid pooling beneath the patient. Prolonged exposure to wet solution may cause irritation or rarely, severe skin reactions. Chemical burns of skin due to pooling may occur.

The diluted solution should be prepared immediately prior to application and should not be stored.

Betadine solution stains can be removed from clothes by washing in hot water; if the stain is severe use a solution of sodium thiosulfate.

5.2. Risk mitigation measures

The treatment of premature babies, newborns, infants or during pregnancy and lactation should be avoided *and should be considered by doctor on base of an individual decision and should be monitored by the doctor.*
Prolonged use may cause skin irritation or severe skin reactions. In the case of local irritation or susceptibility the treatment should be discontinued.

Do not warm up before use. Avoid eye contact.

In some patients with thyroid disorders (eg. goitre, thyroid nodule or other non-acute thyroid disorders), large amounts of iodine intake may induce hyperthyroidism. In these patients Betadine solution should be used for the shortest possible period and the smallest extent. Testing your thyroid function and the doctor's opinion is decisive in these cases.

If signs of hyperthyroidism occur after treatment, test of the thyroid gland is recommended.

The dark brown color of Betadine indicates its effectivity. Faded color indicates a decreasing of the antimicrobial effect.

Decomposition of the solution is facilitated by the light and the temperature above 40 °C.

Betadine solution has an antimicrobial effect between 2 and 7 pH. The PVP iodine complex reacts with proteins and other unsaturated organic compounds, which results in a decrease in their efficacy.

The product should not be used together with enzymatic wound care products or with disinfectants containing mercury, silver, hydrogen peroxide and taurolidine.

The PVP-iodine complex of Betadine solution is incompatible with reducing agents, alkaloid salts and acid responsive substances.

Products containing PVP-iodine used with octenidine-containing antiseptics may cause temporary dark discoloration on the affected areas.

PVP-iodine may interfere with certain diagnostic tests, such as in case of urine or stool hemoglobin or urine glucose testing may cause a false positive result.

With the use of PVP-iodine the iodine absorption of the thyroid may be reduced, which can disturb many tests (thyroid scintigraphy, PBI / protein-bound iodine/ determination, radioiodine determination), and fails the thyroid iodine therapy. After persistent povidone iodine therapy, for objective results thyroid scintigraphy is recommended only after a suitable transition time.

Betadine solution should be used within the expiry date stated on the package.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Do not use:

in case of known sensitivity to iodine, or other components of this product; in case of known thyroid disease, dermatitis, kidney disease; before and after radioactive iodine scintigraphy; during treating of thyroid cancer with radio iodine,.

Side effects:

RARE side effects (1-10 of 10000 user)

Hypersensitivity

Skin Inflammation Due To A Topically Applied Medication (redness of skin, rash, hives and itching)

VERY RARE side effects (1 of 10000 user)

Anaphilactic reactions (severe allergic reaction what can cause breathing difficulty, dizziness and drop in blood pressure)

Hyperthyroidism (what can cause increased appetite, weight loss, sweating, fast heartbeat or restlessness)

Angioedema (severe allergic reaction with swelling of the face and throat).

Side effects with NOT KNOWN FREQUENCY:

- Hypothyroidism (what can cause sleepiness, weight gain, low heart rate) can develop due to prolonged, extensive use of polyvinylpyrrolidone iodine
- Kidney dysfunction
- Chemical burns of skin (in case of prolonged pre-surgery disinfection bath)
- Electrolyte disturbances, metabolic acidosis (acidification of the body), acute kidney injury, osmolality disorder (when large amounts of polyvinylpyrrolidone iodine are absorbed).

Overexposure:

Acute iodine toxicity is manifested by abdominal symptoms , renal dysfunction, circulatory collapse, pulmonary edema and metabolic abnormalities.

If you have an overdose of iodine, contact your doctor immediately.

First aid:

Skin contact: If unintended skin contact occurs remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.

Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with warm water for several minutes. Get medical attention if irritation or vision impairment occurs.

Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.

In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting.

Emergency measures to protect environment:

Hinder substance from entering soil, sewers or living water.

In case of spill adsorb the liquid in a non-flammable material (sand, soil, perlite) and collect in a suitable container for disposal. Wash the effected area with water, and aerate.

5.4. Instructions for safe disposal of the product and its packaging

Dispose of in accordance with state, federal and local regulations.
Do not re-use empty containers.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store below 25°C, in the original packaging, should be protected from light. Do not store under 0 °C, keep away from frost. Shelf life: 3 years.

6. Other information

Chapter 2.2.: AL and SL, can be used in diluted and undiluted form