SCHEDULING STATUS:
S0

PROPRIETARY NAME AND DOSAGE FORM:
POVIDONE-IODINE GEL BIOTECH

COMPOSITION:
Each 1 g of gel contains: Povidone-Iodine 100 mg
Excipients: Citric acid, Disodium Phosphate Dihydrate, Lutrol F127 (Poloxamer 407) and Purified water.

PHARMACOLOGICAL CLASSIFICATION:
A 13.1 Antiseptics, Disinfectants, Cleansing agents.

PHARMACOLOGICAL ACTION:
Povidone-Iodine is an iodophor which slowly liberates inorganic iodine in contact with the skin and mucous membranes. It is a multivalent broad spectrum local antiseptic and exerts an effect against bacteria, fungi, viruses, protozoa, cysts and spores due to the gradual release of the iodine from the base.
Pharmacokinetic Properties
Iodine is slightly absorbed when applied to the skin.
If taken orally, iodine preparations (which are converted to iodide) and iodides are transported to and concentrated in, the thyroid gland.
Iodides not taken up by the thyroid are excreted mainly in the urine with smaller amounts appearing in the faeces, saliva and sweat.
Povidone-Iodine crosses the placenta and is distributed into the breast milk.

INDICATION:
POVIDONE-IODINE GEL BIOTECH is a general antiseptic in the treatment of:
Skin infections
Wounds, cuts and abrasions
Burns if not too extensive
Bedsores
Postoperative wounds

CONTRAINDICATIONS:
Not to be used by patients who are allergic to iodine.
Not to be used during pregnancy or by lactating females
Patients who are sensitive to Povidone-Iodine.
Not to be used on patients with non-toxic nodular colloid goiter or on neonates.

WARNINGS AND SPECIAL PRECAUTIONS:
FOR EXTERNAL USE ONLY. NOT INTENDED FOR INGESTION.
KEEP OUT OF REACH OF CHILDREN.
Absorption of iodine from POVIDONE-IODINE GEL BIOTECH may interfere with tests of thyroid function. (See INTERACTIONS).
Application to large areas of broken skin should be avoided as excessive absorption of iodine may occur.
Hypersensitivity reactions may occur such as irritation and rarely, fever and skin eruptions, in which case use should be discontinued immediately.
POVIDONE-IODINE GEL BIOTECH applied to the skin should not be covered with occlusive dressings.
This disinfectant activity of iodine is reduced by alkalis as well as by protein.
The application of POVIDONE-IODINE GEL BIOTECH to severe burns or to large areas otherwise denuded of skin, may produce the systematic adverse effects associated with iodine and metabolic acidosis, hypernatremia and renal impairment.
Hypothyroidism has occurred in neonates both as a result of absorption of Iodine from Povidone-Iodine applied to the neonate and also to the mother during pregnancy or breastfeeding.
POVIDONE-IODINE GEL BIOTECH application is contraindicated in premature neonates or those weighing less than 1.5 kg.

INTERACTIONS:
Regular or prolonged use should be avoided in patients with thyroid disorders or those receiving lithium therapy. Absorption of povidone-iodine from POVIDONE-IODINE GEL BIOTECH may interfere with thyroid function tests. (See WARNINGS AND SPECIAL PRECAUTIONS).

PREGNANCY AND LACTATION:
Not to be used during pregnancy or by lactating females.
(See PHARMACOKINETIC PROPERTIES)

DOSAGE AND DIRECTIONS FOR USE
Apply POVIDONE-IODINE GEL BIOTECH twice daily or as directed to the cleaned and dried affected area. Cover with a dressing or bandage if required.

SIDE-EFFECTS:
Skin disorders
Less frequent: Hypersensitivity reactions including urticaria, angioedema, cutaneous haemorrhage or purpura, fever, arthralgia, lymphadenopathy, eosinophilia and local irritation may occur. POVIDONE-IODINE GEL BIOTECH can cause hypersensitivity reactions and irritation of the skin and mucous membranes. Severe reactions are rare and POVIDONE-IODINE GEL BIOTECH is considered to be less irritant than iodine.
Renal and urinary disorders
The following side effects have been reported and frequencies are unknown: Severe burns or too large areas otherwise denuded of skin may produce the systemic effects associated with iodine which may include metabolic acidosis, hypernatraemia and renal impairment.
Metabolism and nutrition disorders
The following side effects have been reported and frequencies are unknown:
Hypothyroidism may occur after topical application to neonates. Absorption of povidone-iodine from POVIDONE-IODINE GEL BIOTECH may interfere with thyroid function tests.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Systemic effects including metabolic acidosis, hypernatremia and renal impairment may follow the application of Povidone-iodine to severe burns or large areas otherwise denuded of skin. Treatment is symptomatic and supportive. (See SIDE-EFFECTS AND SPECIAL PRECAUTIONS)
Treatment is symptomatic and supportive.

IDENTIFICATION:
An amber coloured gel with a characteristic odour of iodine.

PRESENTATION:
25 mg tube containing 25 mg of product in an outer carton.
500 ml white HDPE jars containing 500 g of product.

STORAGE INSTRUCTIONS:
Store in an airtight container at or below 25°C. Keep in a dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
38/13.1/0195

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
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SKEDULERING STATUS:
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HANDELSNAAM EN DOSERINGSVORM:
POVIDONE-IODINE GEL BIOTECH

SAMESTELLING:
Elke 1 g jel bevat: Povidoonjodium 100 mg
Hulpstowwe: Sitroensuur, Dinatriumfosfaat dihidraat, Lutrol F127 (Poloxamer 407) en Gesuiwerde water.

FARMAKOLOGIESE KLASSIFIKASIE:
A 13.1 Antiseptika, ontsmettingsmiddels, skoonmaakmiddels.

FARMAKOLOGIESE WERKING:
Povidoonjodium is 'n jodium bevattende antiseptikum wat die anorganiese jodium gelykmatig vrystel wanneer in kontak met die vel en slymvliese kom. Dit is 'n multivalente breë spektrum lokale antiseptikum, wat 'n effek op bakterieë, fungi, virusse, protozoeë, sists en spore uitoefen, as gevolge van die gelykmatige vrystelling van die jodium vanaf die basis.
Farmakokinetiese eienskappe
Jodium word slegs effens geabsorbeer wanneer aan die vel aangewend word. Wanneer jodium middels (wat omgeskakel word tot iodiede) en iodiedes per mond geneem word, word dit vervoer na en gekonsentreer in die skildklier Iodiedes wat nie deur die skildklier opgeneem word nie, word hoofsaaklik in die urine uitgeskei. Kleiner hoeveelhede kan wel in die ontlasting, speeksel of sweet voorkom. Povidoonjodium kruis wel die plasenta en word in borsmelk versprei.

INDIKASIES:
POVIDONE-IODINE GEL BIOTECH is 'n algemene antiseptikum vir die behandeling van:
Vel infeksies
Wonde, snye en skaafplekke
Klein brandwonde
Bedsere
Postoperatiewe wonde

KONTRAÏNDIKASIES:
Moet nie gebruik word in pasiënte met 'n jodium allergie nie.
Moet nie gebruik word tydens swangerskap of deur lakterende vroue nie.
Pasiënte met sensitiwiteit teenoor povidoonjodium.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS:
SLEGS VIR UITWENDIGE GEBRUIK. NIE BEDOEL VIR INGESTIE NIE.
HOU BUITE DIE BEREIK VAN KINDERS.
Absorpsie van jodium vanaf POVIDONE-IODINE GEL BIOTECH mag inmeng met skildklierfunksie toetse. (Sien INTERAKSIES)
Aanwending op groot areas van oop geskaafde vel moet vermy word, aangesien oormatige absorpsie van jodium kan voorkom.
Hipersensitiwiteits reaksies soos irritasie, seldsame koors en veluitbarstings mag voorkom, in welke geval die behandeling onmiddellik gestaak moet word.
POVIDONE-IODINE GEL BIOTECH wanneer aangewend word op die vel, moet nie met water-of lugdigte pleisters of verbande bedek word nie.
Die ontsmettingsmiddel aktiwiteit van jodium word verminder deur alkalieë en proteïene.
Aanwending van POVIDONE-IODINE GEL BIOTECH op erge brandwonde of te groot areas van aangetaste geskaafde vel kan sistemiese adverse effekte veroorsaak, geassosieër met jodium en metabolise asidose, hipernatremie en nierinperking. Hipotiroïdisme kan voorkom in pasgeborenes beide as gevolge van absorpsie van jodium van povidoonjodium aanwending aan die neonaat en ook as gevolge van blootstelling van die moeder tydens swangerskap of borsvoeding.
POVIDONE-IODINE GEL BIOTECH aanwending word teenaangedui in premature pasgeborenes of die wat minder as 1,5 kg weeg.

INTERAKSIES:
Gereelde of verlengde gebruik moet vermy word in pasiënte met tiroïed versteurings of wat litium behandeling ontvang. Absorpsie van povidoonjodium vanaf POVIDONE-IODINE GEL BIOTECH kan inmeng met tiroïedfunksie toetse. (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS)

SWANGERSKAP EN LAKTASIE:
Moet nie gebruik word tydens swangerskap of deur lakterende vroue nie.
(Sien FARMAKOKINETIESE EIENSKAPPE)

DOSERING EN GEBRUIKSAANWYSINGS:
Wend POVIDONE-IODINE GEL BIOTECH twee maal daagliks aan of soos aanwysings op skoon en droë geaffekteerde area. Bedek met 'n pleister of verband indien benodig.

NEWE-EFFEKTE:
Vel versteurings
Minder algemeen: Hipersensitiwiteit reaksies insluitende urtikaria, angioedeem, onderhuidse bloeding of purpura, koors, artralgie, limfadenopatie, eosinofilie en lokale irritasie mag voorkom. POVIDONE-IODINE GEL BIOTECH kan hipersensitiwiteits reaksies en irritasie van die vel en slymvliese veroorsaak. Erge reaksies is seldsaam en POVIDONE-IODINE GEL BIOTECH word minder irriterend as jodium beskou.
Renale en urinêre versteurings
Die volgende newe-effekte is al aangemeld en die frekwensie is onbekend: Erge brand-of te groot areas van geskaafde vel kan sistemiese newe-effekte geassosieer met jodium veroorsaak, wat insluit asidose, hipernatremie en nierinperking.
Metaboliese en voedings versteurings
Die volgende newe-effekte is al aangemeld en die frekwensie is onbekend:
Hipotiroïdisme kan voorkom na topikale aanwending aan pasgeborenes. Absorpsie van povidoonjodium vanaf POVIDONE-IODINE GEL BIOTECH kan inmeng met tiroïedfunksie toetse.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN BEHANDELING DAARVAN:
Sistemiese effekte insluitend metaboliese asidose, hipernatremie en nierinperking, kan volg na aanwending van povidoonjodium aan erge brandwonde of groot areas van geskaafde vel. Behandeling is simptomaties en ondersteunend. (Sien NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREëLS).

IDENTIFIKASIE:
'n Amber-kleurige jel met 'n reuk kenmerkend van jodium.

AANBIEDING:
25 mg wit HDPE buis met 'n plastiek prop, wat 25 mg produk bevat.
500 ml wit HDPE houer wat 500 g produk bevat.

BERGINGSAANWYSINGS:
Bewaar in 'n lugdigte houer teen of benede 25°C.
Bewaar in 'n droë plek.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIE NOMMER:
38/13.1/0195

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