SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hibitane Obstetric Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 1% w/w.
(Incorporated as Chlorhexidine Gluconate Solution Ph. Eur 5.0 v/w)

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

'Hibitane' Obstetric Cream is an antimicrobial preparation for use as an antiseptic and lubricant in obstetric and gynaecological practice.

4.2 Posology and method of administration

Adults

Apply liberally to the skin around the vulva and perineum of the patient, and to the gloved hands of the midwife or doctor.

Elderly and Children

There are no special dosage recommendations for either elderly patients or children.

4.3 Contraindications

'Hibitane' preparations are contraindicated for patients who have previously shown a hypersensitivity reaction to chlorhexidine. However, such reactions are extremely rare.

4.4 Special warnings and precautions for use

For topical application only. Keep out of the eyes and ears and avoid contact with the brain and meninges.

Local stinging and/or chemical burns have been reported following off-label use of gauze packs soaked in Hibitane Obstetric Cream and left intra-vaginally for prolonged periods.

4.5 Interaction with other medicinal products and other forms of interaction

See section 6.2

4.6 Fertility, pregnancy and lactation

There is no evidence of any adverse effects on the foetus arising from the use of 'Hibitane' Obstetric Cream during pregnancy and lactation. Therefore no special precautions are recommended.

4.7 Effects on ability to drive and use machines

None have been reported or are known.

4.8 Undesirable effects

Irritative skin reactions can occasionally occur. Generalised allergic reactions to chlorhexidine including anaphylaxis have also been reported but are extremely rare.

Individual cases of local stinging and/or chemical burns have been reported following off-label use of gauze packs soaked in Hibitane Obstetric Cream and left intra-vaginally for prolonged periods.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Accidental ingestion

Chlorhexidine taken orally is poorly absorbed. Treat with gastric lavage using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is inactive against bacterial spores except at elevated temperatures.

5.2 Pharmacokinetic properties

Because of its cationic nature, chlorhexidine binds strongly to skin mucosa and other tissues and is thus very poorly absorbed. There are, as a consequence, no general pharmacological studies on chlorhexidine available and its effects on internal organs are minimal. No detectable blood levels have been found in man following oral use and percutaneous absorption, if it occurs at all, is insignificant.

5.3 Preclinical safety data

Chlorhexidine is a drug on which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl Alcohol
Cetostearyl Alcohol/Ethylene Oxide Condensate
Isopropyl Alcohol
Linalyl Acetate
Liquid Paraffin
White Soft Paraffin
Purified Water

6.2 Incompatibilities

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with preparations containing chlorhexidine. Chlorhexidine is incompatible with soap and other anionic agents.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

White HDPE bottle containing either 50 ml or 250 ml.

Pack sizes: 1 x 50 ml, 10 x 50 ml, 1 x 250 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Use undiluted

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 19876/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23 January 2003 / 12/01/2007

10 DATE OF REVISION OF THE TEXT

02/07/2021