SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> <STRENGTH> Cream

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains <STRENGTH> of chlorhexidine gluconate.

Excipient with known effect:

<REGARDING THE APPROVAL>

For the full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Cream

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

Chlorhexidine gluconate cream is an antimicrobial preparation for use as an antiseptic and lubricant in obstetric and gynaecological practice.

* 1. 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..

* 1. Contraindications

Chlorhexidine gluconate cream preparations are contraindicated for patients who have previously shown a hypersensitivity reaction to Chlorhexidine. However, such reactions are extremely rare.

* 1. 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 chlorhexidine gluconate cream and left intra-vaginally for prolonged periods.

* 1. Interaction with other medicinal products and other forms of interaction

See section 6.2.

* 1. Fertility, pregnancy and lactation

There is no evidence of any adverse effects on the foetus arising from the use of chlorhexidine gluconate cream during pregnancy and lactation. Therefore no special precautions are recommended.

* 1. Effects on ability to drive and use machines

None have been reported or are known..

* 1. 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 chlorhexidine gluconate 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 Health Product Vigilance Center; HPVC

* 1. 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.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: Dermatologicals, Antiseptics and Disinfectants, Biguanides and amidines, ATC code: D08AC02

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

* 1. 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..

* 1. 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.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. 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..

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>