

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sultrin Triple Sulfa Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sulphathiazole	3.42	% w/w
Sulphacetamide	2.86	% w/w
Sulphabenzamide	3.70	% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Vaginal cream

A smooth white to off-white cream with a characteristic fatty odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of infections caused by *H. vaginalis* and non-specific bacterial vaginitis and cervicitis.

As prophylaxis against post-operative and post-partum local bacterial infections of perineum, vagina and cervix.

4.2 Posology and method of administration

Intravaginal administration.

Adults only:

One applicatorful inserted twice daily for ten days. If necessary, use may be continued thereafter on a once daily basis.

Safety of use in children has not been established.

4.3 Contraindications

Sulphonamide sensitivity.

Kidney disease.

Known hypersensitivity to peanuts.

Throughout pregnancy and during the nursing period because sulphonamides cross the placenta, are excreted in breast milk and may cause kernicterus.

4.4 Special warnings and precautions for use

1. This product is intended for intravaginal use only.

2. Prolonged use of an anti-infective may result in superinfection due to organisms resistant to that anti-infective.
3. The safety and effectiveness for use in children have not been established. Caution should be used in prescribing the product to elderly patients who potentially may have impaired renal function.
4. Patients should be observed for skin rash or evidence of systemic toxicity and, if these develop, the medication should be discontinued.
5. Sultrin Triple Sulfa Cream contains arachis oil (peanut oil) and should not be applied by patients known to be allergic to peanut (See Section 4.3 Contra-indications). As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Sultrin Triple.

4.5 Interaction with other medicinal products and other forms of interaction

Contact should be avoided between contraceptive diaphragms or latex condoms and Sultrin Triple Sulfa Cream since the rubber may be damaged.

4.6 Pregnancy and lactation

The safe use of sulphonamides in pregnancy has not been established. The teratogenic potential of most sulphonamides has not been thoroughly investigated in either animals or humans. However, a significant increase in the incidence of cleft palate and other bony abnormalities of offspring has been observed when certain sulphonamides of the short, intermediate and long-acting types were given to pregnant rats and mice at high oral doses (7 to 25 times the human therapeutic dose).

Because sulphonamides are excreted in breast milk and may cause serious adverse reactions in breast feeding infants, a decision should be made whether to discontinue breast feeding or to discontinue Sultrin, depending on the importance of the drug to the mother.

See 4.3. Contra-indications.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Local irritation and/or allergy have occasionally been reported. As sulphonamides may be absorbed from the vaginal mucosa, the following adverse effects associated with such compounds should be borne in mind:

- Hypersensitivity reactions: skin rashes; severe and potentially fatal skin reactions such as toxic epidermal necrolysis (Lyell's Syndrome) and erythema multiforme bullosa (Stevens-Johnson Syndrome).
- Blood dyscrasias: including agranulocytosis and aplastic anaemia.
- Renal failure.

4.9 Overdose

If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered desirable. Elimination of sulphonamides in the urine may be assisted by giving alkalis such as sodium

bicarbonate and increasing fluid intake.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sulphonamides are structural analogues and competitive antagonists of para-aminobenzoic acid (PABA) and prevent normal bacterial utilisation of PABA for the synthesis of folic acid. Sulphonamides are competitive inhibitors of the bacterial enzyme responsible for the incorporation of PABA into dihydropteroic acid, the immediate precursor of folic acid. The three sulphonamides exert optimal bacteriostatic action at different pH levels as follows:

Sulphathiazole	pH	7.0
Sulphacetamide	pH	5.2
Sulphabenzamide	pH	4.6

5.2 Pharmacokinetic properties

Studies with sulphacetamide and sulphathiazole have indicated that sulphonamides are absorbed in low and variable amounts from the vagina. Once absorbed, sulphonamides become distributed throughout the tissues and pass the placental barrier.

Elimination occurs partly as unchanged drug and partly as metabolites with the major route of elimination via the urine. Small amounts are excreted in the faeces, bile and milk.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arachis oil (peanut oil)
Cetyl alcohol
Cholesterol
Lecithin
Glyceryl monostearate
Wool fat
Methyl parahydroxybenzoate (E218)
Phosphoric acid (E338)
Propylene glycol
Propyl parahydroxybenzoate (E216)
Stearic acid (E570)
Diethylaminoethyl stearamide
Urea
Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube, with polyethylene cap containing 78g or 80g cream.
A plastic applicator is supplied with each pack.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 748/38/1

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