Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ortho-Creme 2%w/w Contraceptive Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tube of cream contains 2% w/w of Nonoxinol 9.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Vaginal Cream
A smooth, white cream with a characteristic lavender odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct to contraception in conjunction with barrier methods of contraception. For use by adult females only.

4.2 Posology and method of administration

For vaginal use.
The cream should be spread over the surface of the diaphragm which will be in contact with the cervix, and on the rim. The diaphragm must be allowed to remain undisturbed for at least six to eight hours after coitus. A fresh application (5 ml) of cream must be made prior to any subsequent act of coitus within this period of time without removing the diaphragm. If a douche is desired, it should be deferred for at least six hours after intercourse. The diaphragm should not be allowed to remain in position for longer than 24 hours.

About 8 cm (3") of cream should be squeezed from the tube on to the side of the diaphragm which will contact the cervix. This should be spread evenly over the surface of the dome and all around the rim. To facilitate insertion, a small additional amount may be spread over the other side of the dome.

4.3 Contraindications

Use in the presence of hypersensitivity.
Patients with absent vaginal sensation, e.g. paraplegics and quadriplegics.

4.4 Special warnings and precautions for use

Spermicidal intravaginal preparations are intended for use in conjunction with barrier methods of contraception such as condoms, diaphragms and caps.

This product is merely an adjunct to contraception. Where avoidance of pregnancy is important, the choice of contraception method should be made in consultation with a doctor or a family planning clinic.

This product does not protect against HIV (AIDS) or other sexually transmitted diseases (STDs). A latex condom should be used to protect against the spread of STDs.

High frequency use of nonoxinol-9 has been reported to cause epithelial damage and increase the risk of HIV infection. Therefore women at risk of HIV/STD infection and who have multiple daily acts of intercourse should be advised to choose another method of contraception. Sexually active women should consider their individual HIV/STD infection risk when choosing a method of contraception.

If vaginal or penile irritation occurs, discontinue use. If symptoms worsen or continue for more than 48 hours, medical advice should be sought.

The diaphragm should not remain in position for more than 24 hours.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is no evidence from animal and human studies that nonoxinol-9 is teratogenic. Human epidemiological studies have not shown any firm evidence of adverse effects on the foetus, however, some studies have shown that nonoxinol-9 may be embryotoxic in animals. This product should not be used if pregnancy is suspected or confirmed.

Animal studies have detected nonoxinol-9 in milk after intravaginal administration. Use by lactating women has not been studied.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

May cause irritation of the vagina or penis.

4.9 Overdose

Ortho-Creme Contraceptive Cream is intended for intravaginal use only. If excess quantities are taken orally by mistake this may give rise to gastric irritation as the product contains a surfactant. General supportive therapy should be carried out if necessary. Hepatic and renal function should be monitored if medically indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The standard *in vitro* test (Sander-Cramer) evaluating the effect of nonoxinol-9 on animal sperm motility has shown the compound to be a potent spermicide.

The site of action of nonoxinol-9 has been determined as the sperm cell membrane. The lipoprotein membrane is disrupted, increasing permeability, with subsequent loss of cell components and decreased motility. A similar effect on vaginal epithelial and bacterial cells is also found.

5.2 Pharmacokinetic properties

The intravaginal absorption and excretion of radio labelled (^{14}C) nonoxinol-9 has been studied in non-pregnant rats and rabbits and in pregnant rats. No appreciable difference was found in the extent or rate of absorption in pregnant and non-pregnant animals.

Plasma levels peaked at about one hour and recovery from urine as unchanged nonoxinol-9 accounted for approximately 15-25% and faeces approximately 70% of the administered dose as unchanged nonoxinol-9. Less than 0.3% was found in the milk of lactating rats. No metabolites were detected in any of the samples analysed.

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

Benzoic acid (E210)
Cetyl alcohol
Lavender compound 13091 (contains Benzyl Benzoate)
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Propylene glycol
Carmellose Sodium
Sodium laurilsulfate
Stearic acid
Trolamine
Acetic acid glacial
Castor oil, virgin
Potassium hydroxide
Sorbic acid (E200)
Purified water

6.2 Incompatibilities

Not applicable.

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

Epoxy resin lined aluminium tubes 70 g with polyethylene caps.

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

Janssen-Cilag Limited
Saunderton
High Wycombe
Buckinghamshire
HP 14 4HJ
UK

8 MARKETING AUTHORISATION NUMBER

PA 748/35/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 July 1983

Date of last renewal: 28 July 2003

10 DATE OF REVISION OF THE TEXT

December 2005