Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Noritate 1% w/w cream.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Metronidazole 10mg/g (1%w/w)

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream.
A white to creamy-white cream with soft consistency.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of rosacea.

4.2 Posology and method of administration

Adults (including the elderly): Noritate should be applied once daily, for eight weeks, to the affected areas of freshly cleansed skin. Further treatment may be necessary depending on the severity of the condition.

Children: It is not recommended for paediatric patients (aged 16 years and under).

4.3 Contraindications

Noritate is contraindicated in individuals who have shown hypersensitivity to metronidazole, parahydroxybenzoates or any of the other ingredients.

4.4 Special warnings and precautions for use

Metronidazole has been reported to cause watering of the eyes, therefore contact with the eyes should be avoided. If a reaction suggesting local irritation occurs, patients should be directed to use the medication less frequently or discontinue use temporarily until further instructed.

Metronidazole is a nitroimidazole and should be used with care in patients with evidence of, or a history of, blood dyscrasia.

Exposure to strong sunlight or UV light should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

Oral metronidazole has been reported to potentiate the anticoagulant effect of coumarin and warfarin resulting in a prolongation of prothrombin time. Drug interactions are less likely with topical administration, but should be kept in mind when Noritate is prescribed for patients who are receiving anticoagulant treatment. Oral metronidazole also interacts with alcohol, producing a disulfiram-like reaction. Although this response has not been reported with topically applied metronidazole, an interaction with alcohol may be a possibility.

4.6 Pregnancy and lactation

The safe use of metronidazole during pregnancy or lactation has not been established therefore Noritate should only be used in pregnancy where there is no other alternative. Metronidazole crosses the placental barrier to the foetus and is excreted in breast milk, however, blood levels for topical administration are significantly lower than for oral administration. A decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Reported adverse reactions include transient skin irritation, dryness and stinging. Very occasionally contact dermatitis has been reported. Gastrointestinal effects have sometimes been reported with metronidazole, however, for topical administration these are likely to be less common and less severe than for oral administration.

4.9 Overdose

There have been no clinical reports of overdosage. Supportive therapy should be initiated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D06B X01 (Other chemotherapeutics)

Noritate is particularly effective against the inflammatory papulopustular component of rosacea. The mechanisms by which Noritate act in reducing inflammatory lesions of rosacea are unknown, but may include an anti-bacterial and/or anti-inflammatory effect.

5.2 Pharmacokinetic properties

Noritate has a local action on the skin. Percutaneous absorption of topically applied metronidazole is minimal. Following a single application of ^{14}C-metronidazole in a 2% cream formulation, no plasma levels could be detected in subjects with intact skin and in only one subject with stripped skin. 1.3% urinary radioactivity was detected.

5.3 Preclinical safety data

Metronidazole is a well established drug substance, therefore there are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic acid
Glyceryl monostearate
Glycerol
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Triethanolamine
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

Tube with screw cap containing 3.5g, 30g or 60g of cream.

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

None.

7 MARKETING AUTHORISATION HOLDER

Sanofi-aventis Ireland Ltd.
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 0540/135/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 May 1997

Date of last renewal: 19 May 2002

10 DATE OF REVISION OF THE TEXT

October 2006