Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zostrum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Idoxuridine 5% w/v.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cutaneous Solution

A clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of the cutaneous lesions of herpes zoster.

4.2 Posology and method of adminstration

For topical use.

Recommended dosage
This product should be painted on the lesions and their erythematous bases four times daily for four days. Treatment should start as soon as the condition has been diagnosed, ideally within two or three days after the rash appears.

4.3 Contraindications

(i) Use in patients hypersensitive to either of the ingredients.

(ii) Use on herpes zoster lesions affecting the eye or adnexa.

4.4 Special warnings and special precautions for use

(i) The hands should be thoroughly washed after applying the substances as should any other body surface which it has accidentally contacted.

(ii) The product should be applied carefully and sparingly only to the sites actually involved, and for the recommended period only.

4.5 Interaction with other medicinal products and other forms of interaction

Since the solvent facilitates absorption of many substances, no other topical medication should be used on the site simultaneously.

4.6 Pregnancy and lactation

Idoxuridine has been shown to be teratogenic in animal studies. The drugs should not be used during pregnancy or in women at risk of pregnancy.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side effects include local stinging rash and a distinctive taste.

4.9 Overdose

There is no clinical evidence of overdosage. Standard supportive measures should be adopted.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Idoxuridine is an antiviral agent which acts by blocking the uptake of thymidine into the deoxyribonucleic acid (DNA) of the virus and inhibits replication of viruses such as adenovirus, cytomegalovirus, herpes simplex (herpes virus hominus), varicella zoster or herpes zoster (herpes virus varicella) and vaccinia. It has no action against latent forms of the virus. It does not inhibit RNA viruses such as influenza virus or poliovirus.

5.2 Pharmacokinetic properties

The idoxuridine is dissolved in dimethyl sulphoxide which penetrates the skin and carries the antiviral agent to the deeper levels of the epidermis where the virus is replicating.

Idoxuridine is rapidly metabolised in the body to iodouracil, uracil and iodine which are rapidly excreted in the urine.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl sulphoxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf life expiry date for this product shall not exceed two years from the date of its manufacture.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate.
Keep container in the outer carton.

6.5 Nature and contents of container

5ml Class III amber glass bottle. White urea/formaldehyde cap with polycone liner. Black urea/formaldehyde cap with polythene/nylon brush insert – for patient use.

6.6 Instructions for use and handling

Instructions for use:

1) Carefully unscrew the white cap and discard. Replace it with the black cap and brush.

2) Seal the bottle tightly after use.

3) Discard any solution remaining in the bottle as soon as the treatment period is complete.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 590/17/1

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