**SUMMARY OF PRODUCT CHARACTERISTICS**

1. **NAME OF THE MEDICINAL PRODUCT**

<Trade Name><Strength> Cream

1. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Hydroquinone <Strength> w/w

1. **PHARMACEUTICAL FORM**

Topical Cream

1. **CLINICAL PARTICULARS** 
   1. **Therapeutic indications**

For Topical Administration

For reducing hyperpigmentation of skin, such as persistent freckles and brown marks (lentigines) and irregular pigmentation of negroid skin.

* 1. **Posology and method of administration**

Adults and Elderly:

Apply twice daily after washing, until pigmentation has been reduced (depending on skin type, for 6-16 weeks). Then twice weekly.

Children:

Not for use on children, unless under the direction of a physician.

* 1. **Contraindications**
* Known hypersensitivity to any of the ingredients.
  1. Special warnings and precautions for use
* Not suitable for red marks.
* Do not use on broken skin or near eyes.
* For external use only.
* Keep medicines away from children. Discontinue if eczema or irritation occurs, or if darkening reoccurs during treatment.
  1. **Interaction with other medicinal products and other forms of interaction**

None known

* 1. **Pregnancy and lactation**

No undesirable effects known during pregnancy or lactation but contact between treated skin and infants is to be avoided.

* 1. **Effects on ability to drive and use machines**

None known

* 1. **Undesirable effects**

Irritation and subsequent hypersensitivity have been observed but are rare for creams at less than 5% Hydroquione. Ochronosis and pigmented colloid milium have been reported following extended use of stronger creams in a high sunshine climate (South Africa). Such severe effects are preceded by redarkening of the skin and follow continual administration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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, Thai FDA.

* 1. **Overdose**

None known as regards topical application. If accidently ingested, treat symptomatically.

1. **PHARMACOLOGICAL PROPERTIES** 
   1. **Pharmacodynamic properties**

Hydroquinone interferes with the production of new melanocytes and hence the bleaching effect on pigmented skin progresses slowly and evenly.

* 1. **Pharmacokinetic properties**

Effects on pigmented skin are normally observed by 6 weeks from initiation of the hydroquinone treatment. The time varies according to skin type.

* 1. **Preclinical safety data**

No additional information to that already included elsewhere in the SPC.

1. **PHARMACEUTICAL PARTICULARS** 
   1. **List of excipients**

<Regarding the approval>

* 1. **Incompatibilities**

<Regarding the approval>

* 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 TEXT[[1]](#footnote-1)**

<Regarding the approval>

1. Ref: Symba, MHRA, date 11/10/2006 [↑](#footnote-ref-1)