Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Robinul 100% w/w Powder for Solution for Iontophoresis.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Robinul Powder consists of 100% w/w Glycopyrronium Bromide.
When reconstituted as directed, the final solution for iontophoresis should contain 0.5mg/ml (0.05% w/v solution) of glycopyrronium bromide.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for Solution for Iontophoresis
White, crystalline powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Iontophoretic treatment of the plantar and palmar skin for idiopathic hyperhidrosis.

4.2 Posology and method of administration

A 0.05% solution in distilled water of Glycopyrrolate USP is applied to palmar or plantar skin. When treating the foot or hand sufficient solution to cover the palm or sole is placed in a non-metallic container and the anode, of sheet metal larger in area than the part being treated, is placed in the solution. The sole or palm is separated from the anode by 5 mm of plastic foam or a layer of lint or sponge sheet.

In all cases an electrical circuit is completed by placing another limb in lukewarm tap water containing the cathode, similarly shielded from direct contact with the skin.

Recommended average conditions are 90 volts DC at 10-20 mA for adults (including older patients) and 2-10 mA for children, for 12 minutes at each site, depending on the patient's skin tolerance, body weight and size. Only one site should be treated at a time and only two sites in any one day. Treatments should not be repeated within seven days, but may be repeated later varying the precise conditions according to the recurrence and severity of hyperhidrosis. See also 'Special warnings and special precautions for use' below.

4.3 Contraindications

Hypersensitivity to Glycopyrronium Bromide.
Glaucoma and Pregnancy

4.4 Special warnings and precautions for use

This product should be used with great caution in patients with cardiovascular disease, thyrotoxicosis and obstructive disorder of the lower urinary tract.

Patients with mycotic or other skin infection should not be treated.

Exercise care in patients with prostatic hypertrophy. Due to the effect of anticholinergics on mucous secretions, it is

advisable not to treat people with chronic bronchitis.

A mild tingling feeling may occur in the immersed areas during treatment and any recent cuts or cracks in the skin may smart when the current is increased at the start of iontophoresis. The latter can be avoided by covering the lesion with a thin smear of petroleum jelly.

Avoid over-exertion, especially in hot weather, until any side-effects have disappeared.

The product should only be used by specialist units experienced in iontophoretic technique.

The electrodes and treated skin areas must be placed in non-metallic containers and separated carefully by layers of, for example, sponge or lint. Direct contact between electrodes and skin must be avoided, otherwise burns can result. The current must be very slowly increased from zero mA and decreased to zero mA at the beginning and end of the treatment period respectively to avoid any Faradic discharge between the electrode and skin on removal of the patient's limb from the container of solution. Instruct patients that contact must not be broken during treatment.

There is only limited experience of the use of this product in children.

4.5 Interaction with other medicinal products and other forms of interaction

The solution must not be alkaline; otherwise the glycopyrrolate will hydrolyse more rapidly.

4.6 Fertility, pregnancy and lactation

Do not use during pregnancy or lactation as safety in these conditions has not been established. Reproduction studies in rats and rabbits revealed no teratogenic effects from glycopyrrolate. However, diminished rates of conception and of survival at weaning were observed in rats, in a dose related manner. Studies in dogs suggest that this may be due to diminished seminal secretion which is evident at high doses of glycopyrrolate. The significance of this for man is not clear.

4.7 Effects on ability to drive and use machines

Since this drug may cause drowsiness, patients receiving glycopyrrolate should not drive or operate machinery immediately after treatment unless it has been shown not to affect their physical or mental ability.

4.8 Undesirable effects

Immune system disorders - Hypersensitivity reactions, including anaphylaxis have been reported.

Eye disorders - Blurred vision

Cardiac disorders - Glycopyrrolate may cause tachycardia

Gastrointestinal disorders - Dryness of the mouth and mild abdominal discomfort may occur. Occasionally difficulty in eating may occur.

Renal and urinary disorders – Micturition may be temporarily affected for some hours after treatment. (See also 4.4 Special warnings and special precautions for use).

General disorders and administration site conditions – A mild tingling feeling may occur in the immersed areas during treatment and any recent cuts or cracks in the skin may smart when the current is increased at the start of iontophoresis. The latter can be avoided by covering the lesion with a thin smear of petroleum jelly. Avoid over-exertion especially in hot weather, until any side effects have disappeared.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Robinul Powder contains glycopyrrolate, a quaternary ammonium antimuscarinic agent.

5.2 Pharmacokinetic properties

Quaternary ammonium anticholinergic agent highly ionised at physiological pH with resulting poor penetration of brain and placental barriers. Glycopyrrolate is excreted in bile and urine.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

As packaged for sale: 4 years.
After reconstitution according to directions: 14 days.

6.4 Special precautions for storage

Do not store above 25°C. Keep the bottle tightly closed.

6.5 Nature and contents of container

The product is presented in screw cap amber glass bottle (Ph.Eur. Type III), containing 3, 5 or 10 grams of glycopyrrolate USP.

Not all pack sizes may be marketed

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

The product should only be used by specialist units experienced in iontophoretic technique. The electrodes and treated skin areas must be placed in non-metallic containers and separated carefully by layers of, for example, sponge or lint. Direct contact between electrodes and skin must be avoided otherwise burns may result. The current must be very slowly increased from zero mA and decreased to zero mA at the beginning and end of the treatment period respectively

to avoid any Faradic discharge between the electrode and skin on removal of the patient's limb from the container of solution. Instruct patient that contact must not be broken during treatment.

When using Robinul Powder 3gm pack, prepare a stock solution of Robinul prior to use by dissolving 3gm of Robinul Powder in 600ml (0.6 litre) of freshly boiled and cooled distilled or deionised water. This will result in a solution of 0.5% w/v.

When using Robinul Powder 5gm pack, prepare a stock solution of Robinul prior to use by dissolving 5gm of Robinul Powder in 1000ml (1 Litre) of freshly boiled and cooled distilled or deionised water. This will result in a solution of 0.5% w/v.

When using Robinul Powder 10gm pack, prepare a stock solution of Robinul prior to use by dissolving 10gm of Robinul powder in 2000ml (2 litre) of freshly boiled and cooled distilled or deionised water. This will result in a solution of 0.5% w/v.

100ml of the stock solution should then be diluted with 900ml of freshly boiled and cooled distilled or deionised water so as to form a solution of 0.05% w/v which can then be used for the purpose of iontophoresis.

The reconstituted solution for iontophoresis is clear and colourless in appearance.

Glycopyrrolate does hydrolyse slowly at pH 7 and it is recommended that stock solutions be discarded after not more than 14 days.
The solution must not be alkaline otherwise glycopyrrolate will hydrolyse more rapidly.

There are no special requirements for disposal of this medicinal product once used.

7 MARKETING AUTHORISATION HOLDER

MercuryPharm Ltd
4045, Kingswood Road,
City West Business Park,
Co Dublin

8 MARKETING AUTHORISATION NUMBER

PA 857/1/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 August 1978

Date of last renewal: 25 August 2008

10 DATE OF REVISION OF THE TEXT

April 2012