



SUMMARY OF PRODUCT CHARACTERISTICS

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

Robinul Powder.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Robinul Powder consists of Glycopyrrolate (glycopyrronium bromide) 100% w/w.

3. PHARMACEUTICAL FORM

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

Route of Administration: Iontophoresis

Dosage and 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 5mm 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. Contra-indications

Glaucoma. Do not use during pregnancy.

4.4. Special warnings and precautions for use

Glycopyrrolate may cause tachycardia.

This product should be used with great caution in patients with cardiovascular disease, thyrotoxicosis and obstructive disorders of the lower urinary tract. Patients with mycotic or other skin infections should not be treated.

4.5. Interactions with other medicinal products and other forms of interaction

Not applicable.

4.6. Pregnancy and lactation

Do not use during pregnancy, as safety in this condition 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

Dryness of the mouth, blurred vision and mild abdominal discomfort may occur. 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. Occasionally difficulty in eating may occur and micturition may be temporarily affected for some hours after treatment. 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 appropriate for the product.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Glycopyrrolate is an anticholinergic agent. The pharmacological particulars of anticholinergic drugs are well documented in the scientific literature.

5.2. Pharmacokinetic properties

This product is indicated for use by Topical Iontophoresis for hyperhidrosis. Glycopyrrolate is a Quaternary Ammonium Compound and as such is absorbed through the skin in negligible amounts only.

5.3. Preclinical safety data

Nothing of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Not applicable - no other constituents present.

6.2. Incompatibilities

None.

6.3. Shelf life

48 months unopened. 14 days after reconstitution.

6.4. Special precautions for storage

There are no special storage precautions for this product.

6.5. Nature and contents of container

The product is presented in a screw cap amber bottle containing 3, 5 or 10g of glycopyrrolate USP.

6.6. Instructions for use/handling

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. Prior to use in iontophoresis a stock solution of Robinul powder (glycopyrrolate) may be made up with freshly boiled and cooled distilled or deionised water. 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.

ADMINISTRATION DETAILS

7. MARKETING AUTHORISATION HOLDER

Anpharm Limited
Roscrea
Co. Tipperary
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

PL 15372/0003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st July, 1997.

10. DATE OF (PARTIAL) REVISION OF THE TEXT

May, 2003.