Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

APPLICATION FOR RECLASSIFICATION OF REGAINE FOR WOMEN ONCE A DAY SCALP FOAM 5% CUTANEOUS FOAM FROM POM TO P

LAY OVERVIEW

1. INTRODUCTION

The marketing authorisation holder, McNeil Products Ltd, applied to make Regaine for Women Once a Day Scalp Foam 5% w/w Cutaneous Foam available as a pharmacy medicine, for supply without prescription from pharmacies under the supervision of a pharmacist.

The Medicines and Healthcare products Regulatory Agency (MHRA) considers this product is safe enough to be sold without prescription under the supervision of a pharmacist.

See the public assessment report for Regaine for Women Once a Day Scalp Foam.

2. BACKGROUND

Regaine for Women Once a Day Scalp Foam 5% w/w Cutaneous Foam contains minoxidil.

Minoxidil is used either in tablets for the treatment of high blood pressure or in topical solutions or foams to apply to the scalp for the treatment of male or female pattern hair loss. It has been available as a solution for the treatment of male and female pattern hair loss since 1988. A 5% foam treatment for men was licensed in 2010.

Minoxidil topical products were originally available as Prescription Only Medicines (POM). Since 1994, a number of reclassification applications have been made resulting in increased availability of minoxidil without prescription, initially as a Pharmacy (P) medicine, available for sale without prescription in pharmacies under the supervision of a pharmacist and laterally as a General Sales List (GSL) medicine, available for sale also in non-pharmacy retail outlets

Minoxidil is the only drug licensed in the UK for non-prescription use in the treatment of male and female pattern hair loss. Currently:

- A 2% solution is available for men and women as a GSL medicine in a maximum pack size of 1 x 60ml, to be used twice daily
- A 5% solution and 5% foam are available for men as GSL medicines in a maximum pack size of 1 x 60mls and 3 x 73mls respectively

3. PROPOSED TERMS OF RECLASSIFICATION

The applicant has proposed the following conditions for the pharmacy availability of Regaine for Women Once a Day Scalp Foam 5% w/w Cutaneous Foam:

- For external use
- Maximum strength 5%
- For the treatment of female pattern hair loss in women between 18 and 65
- Maximum dose of 1g (equivalent to 50mg minoxidil) to be applied daily
- Maximum pack size of 2 x 73mls (equivalent to 2 x 60g product providing 120 days' supply)

The approved SmPC and the patient information leaflet are available on the MHRA website.

The applicant's overall rational for the reclassification is that a daily dose for women of 1g of 5% minoxidil topical foam, has been shown to be equivalent to a twice daily dose of 1ml of 2% minoxidil topical solution and that a daily application of the foam would be more acceptable and convenient to women than a twice daily application of the solution.

4. PRESCRIPTION ONLY MEDICINE CRITERIA

Under the provisions of The Human Medicines Regulations 2012, regulation 62 in Part 4 of the Human Medicines Regulations 2012 [SI 2012/1916] sets out the criteria which require a medicine to be classified as available only on prescription. These are that the medicine:

- Is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist;
- Frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;
- Composed of substances, or preparations of substances, of which the activity requires, or the side effects require, further investigation;
- Intended for parenteral administration.

These four conditions are referred to as the POM criteria

1. ASSESSMENT OF SUITABILITY FOR PHARMACY AVAILABILITY

The MHRA assessed the application against the POM criteria, stated in Section 4.

5.1 1st POM Criterion

Likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor

5.1.1 Direct danger to health

Topical minoxidil has a well-established safety profile. There is extensive experience in both P and GSL settings of twice daily use of minoxidil solution and foam in men, and of twice daily use of 2% minoxidil solution in both men and women.

A once daily application of Regaine for Women Once a Day Scalp Foam 5% w/w Cutaneous Foam has the same amount of absorption of minoxidil from the skin into the blood stream as twice daily use

of 2% solution, which means that the two products have the same level of risk of adverse effects resulting from the drug getting into the bloodstream.

From an analysis of adverse events reported by patients/consumers, healthcare professionals and health authorities, and a review of product safety data undertaken by the applicant there is no evidence of a change in the safety profile of the 2% solution for women since it was reclassified from P to GSL in 2004.

5.1.2 Indirect danger to health

There are no indirect dangers associated with the use of this product regarding the risk of masking other diseases and therefore delaying a doctor's diagnosis and subsequent treatment.

5.2 2nd POM criterion

Is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health

There is no evidence of frequent or widespread incorrect use of topical minoxidil. There are no particular concerns regarding overdose. In terms of quantity of product available in one pack there is already a 3 x73ml pack size of 5% foam available for men as a GSL medicine, which is larger than the proposed pack size for Regaine for Women Once a Day Scalp Foam 5% w/w Cutaneous Foam as a P medicine.

5.3 3rd POM criterion

Contains substances or preparations of substances of which the activity requires, or the side effects require, further investigation

Topical minoxidil was first licensed in 1988 and has been available as a non-prescription medicine since 1994. The activity and safety of topical minoxidil is well established. Two questions were raised during assessment in relation to the adverse events reported and these have been satisfactorily addressed. There were no new major findings bearing on the established overall safety profile of topical minoxidil products during the last safety reporting period (March 2010 – March 2013).

5.4 4th POM criterion

Is normally prescribed for parenteral administration

This product is for topical use only, so this criterion does not apply.

6. SPECIFIC RISK MINIMISATION MEASURES

A potential risk was identified that women could mistakenly use the product twice daily since all other topical minoxidil products on the market are for twice daily use. However, this has been satisfactorily addressed in the product name and by clear warnings on the label and leaflet. Also, as the product will be classified as a P medicine additional advice on correct use will also be available from the

pharmacist. In any case, there is no major health concern if a woman mistakenly used the product twice daily.

7. CHM ADVICE

CHM advice was not required for this application for the following reasons:

- Neither female pattern hair loss nor topical minoxidil is new in the non-prescription setting. Twice daily 2% topical minoxidil solution has been available as a P medicine for the treatment of female pattern hair loss for over 20 years and a GSL medicine for 13 years
- Treatment with once daily 5% Foam is non-inferior, both in efficacy and safety to twice daily 2% minoxidil solution
- The safety data reveals no new safety concerns since the product has been available without prescription. Systemic absorption with once daily 5% minoxidil foam has been shown to be the same as twice daily 2% minoxidil solution
- The Applicant has provided suitable justification for the maximum pack size of 2 x 73mls) in relation to the nature of the treatment. Since a 3 x 73ml pack size is already available for men as GSL there are no safety concerns about availability of this amount of product in one pack as a P medicine.
- In view of the similarity between twice daily 2% minoxidil solution, which is classified as GSL, and once daily 5% minoxidil foam, which will be classified as P, except for the longer length of treatment with Foam which has resulted from the use of daily dose, there is nothing new for CHM to consider

7. PUBLIC CONSULTATION ON PHARMACY AVAILABILITY OF REGAINE FOR WOMEN ONCE A DAY SCALP FOAM 5% CUTANEOUS FOAM

In addition to the points set out in section 8, public consultation is not required for this application for the following reasons:

- From a public and healthcare professional perspective the foam will be a more acceptable choice for women because of its once daily dose and reduced the likelihood of causing hypertrichosis (facial hair growth) caused by the product running off the head and onto the face
- Although this will be the first time a minoxidil product will be available with a once daily dose, satisfactory measures have been put in place to manage the risk of users already familiar with existing minoxidil products using it twice daily. These measures include: the choice of product name; information and warnings on the label and leaflet; the provision of pharmacy support material; and restricting the classification to pharmacy only supply.

9. CONCLUSION

The proposal to reclassify Regaine for Women Once a Day Scalp Foam 5% w/w Cutaneous Foam as a P medicine is acceptable under the following conditions:

- For the treatment of alopecia androgenetica in women (also known as female pattern hair loss) in women between 18 and 65
- Maximum dose:1g of product to be applied to the total affected areas of the scalp once daily
- Maximum pack size: 2 x 73 mls (2 x 60g minoxidil) – 120 days