



# Management of hair loss: Best practice guidance

Next month McNeil Products is launching Regaine® for Men Extra Strength Scalp Foam 5% w/w Cutaneous Foam (minoxidil), a new format of minoxidil hair loss treatment. The product will be marketed to young men who are starting to lose their hair. It will be available in both P and GSL packs.

Pharmacy Magazine recently convened an Advisory Forum, sponsored by McNeil, to discuss the new format. The Forum members agreed that the product is an important professional and commercial opportunity for pharmacy.

**M**ale pattern baldness, or androgenetic alopecia, is the most common type of hair loss. It is an inherited condition accounting for 95 per cent of cases of hair loss in men. This type of hair loss generally starts with recession of the temple hairline, followed by thinning over the crown.

The rate of hair loss is extremely variable. Some men go completely bald in less than five years but most take 15-25 years.<sup>1</sup> Around 40 per cent of men show noticeable hair loss by the age of 35 years and some 70 per cent of men who are losing their hair want to do something about it.<sup>2</sup>

Hair loss in such cases is caused by changes to the normal hair cycle. Hair follicles shrink, causing a shortening of the growing phase (anagen) and an increase in the resting phase (telogen, the phase in which hair shedding occurs).

Other types of hair loss, for which topical minoxidil is not suitable and medical referral is needed, are shown in the table on page 4.

Minoxidil is a peripheral vasodilator that was introduced in the 1970s for treatment of hypertension. Hirsutism was seen as a side-effect and this led to development of Regaine® scalp solution, which has been available as an

OTC product since 1996. It is not certain how the drug stimulates hair growth but the mechanism is thought to involve:

- Increasing the diameter of the hair shaft
- Prolonging the hair growth phase
- Stimulating recovery from the resting phase
- Increase of blood flow to the hair follicle

## REGAINE® FOAM

Regaine® Foam is a 5% formulation of minoxidil. It is licensed for use in men aged 18 to 49 years (the age group for which clinical trial data are available). The new product has been very successful in the US, where it has been available since 2006.

The foam is easier to use than the original Regaine® scalp solution and more cosmetically acceptable. It is a thermolabile formulation that melts at body temperature. It should be used twice daily and massaged lightly into the scalp, where it is absorbed. The product is unperfumed.

The foam should be applied to a dry scalp. Styling products can also be used but they should be applied after the foam. Systemic absorption of minoxidil is low but use should be stopped if the man notices signs of hypotension or other cardiovascular symptoms (such as chest pain or tachycardia).

For product information, refer to the back page.



Developed in partnership  
with McNeil,  
manufacturers of  
**Regaine®**



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MRPharms  
Director at Ista Health; Research Fellow, Medicines Management at Keele University (chairman)



**Peter Cattee MRPharms**  
managing director,  
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**David Mitchell**  
head of pharmacy,  
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**Nicola Osborne**  
MRPharms  
proprietor, Park Lane Pharmacy,  
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Regaine® Foam was evaluated in a US placebo-controlled trial in 352 men (mean age 39 years)<sup>3</sup> that reported a statistically significant increase in hair counts and subjective assessment of improved hair loss. Overall, 90 per cent of men in the trial using active treatment said that they kept or regrew hair on evaluation at week 16. Safety assessment up to one year showed the treatment to be well tolerated.

John Blenkinsopp commented: "From the clinical data, it appears that men keep what hair they have got even if they do not necessarily regrow hair, highlighting the importance of early use of Regaine®."

Marilyn Sherlock added that in her experience some men do not mind if their hair does not regrow as long as progression of hair loss stops.

### KEY CONSULTATION POINTS

The Advisory Forum agreed that pharmacy staff should discuss Regaine® Foam treatment with their customers to ensure proper use and so increase the chance of positive results.

Points that need to be emphasised:

- Regaine® Foam must be used twice a day every day, once in the morning and once in the evening (about half an hour before going to bed)
- No benefit should be expected before eight weeks — it is important to manage customers' expectations so they do not stop use prematurely
- It is not unusual to shed hair near the beginning of the therapy — this is most likely due to minoxidil's action of shifting hairs from the resting phase to the growing phase (old hairs fall out as new hairs grow in their place). Increase in hair shedding generally occurs two to six weeks after beginning treatment and subsides within a couple of weeks
- First hair regrowth may be downy — with time, texture should become the same as normal hair
- At 16 weeks of continued twice daily use, the majority of men will see regrowth or stabilisation of their hair loss
- Treatment needs to be continued to maintain efficacy — topical minoxidil only works as long as it is used. When treatment stops, the new hairs are shed.

### PHARMACY ROLE IN THE MANAGEMENT OF HAIR LOSS

The Advisory Forum agreed that the new treatment meets a consumer need and that pharmacists should engage with it.

They noted that for many men hair loss is a sensitive area that requires empathetic handling by pharmacy staff. The Regaine® pharmacy training aid and support materials should give pharmacists and their

## marketing and pharmacy training

Regaine® Foam will be marketed by McNeil as a lifestyle product that is licensed and clinically proven.

It will be available in single (GSL) and triple (P) packs. The triple pack has a cost advantage and is expected to account for the vast majority of sales. Product advertising will highlight this pack and promote pharmacy supply. It will also emphasise the need for continued treatment to obtain and maintain benefit.

The company's target consumers are men aged 25-44 years who are starting to lose their hair and want to do something about it. The foam is packaged as a male grooming product.

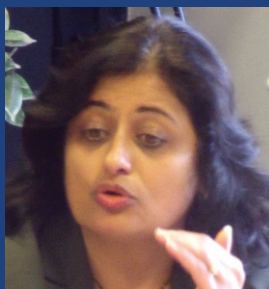
In contrast, Regaine® scalp solution has been positioned more as a medicinal product, for men in their late 40s/early 50s. This product remains available and is expected to have continued use by men who already like the product.

Pharmacy training materials for Regaine® Foam will be available this month [January] from McNeil, with the product launch mid-February. Pharmacies that have completed the training pack will be listed on the Regaine® consumer website.

To take the training online, or to order free display material, you can visit [www.regaine.co.uk/hcp](http://www.regaine.co.uk/hcp).



**Marilyn Sherlock FIT MAE**  
Chair, Institute of Trichologists



**Samixa Shah MRPharmS**  
clinical pharmacist and consultant



**Graham Phillips MRPharmS**  
owner, Manor Pharmacy Group,  
Hertfordshire



**Noel Wicks MRPharmS**  
proprietor, Right Medicine Company,  
Stirling

staff the confidence to talk to customers about the product.

There was a feeling that any reluctance among pharmacists and their staff to sell new OTC products often comes down to lack of confidence. Noel Wicks said: "Pharmacists need confidence, and this comes if we are well supported with good information." He described Regaine® Foam as "a reinvigoration of a very good pharmacy product."

Minoxidil is the only licensed OTC treatment for hair loss. Although the treatment is relatively expensive — equivalent to around half-pint of beer a day — the Forum highlighted the alternatives that might be used. Marilyn Sherlock pointed out: "There are thousands of 'miracle cures' for hair loss that have had no proper clinical trials and do not work. People will buy these products for months on end, paying around £50 a month."

Picking up this point, John Blenkinsopp added: "Pharmacy staff who are reticent to recommend 'expensive' products should note that men currently waste a great deal of money on products that do not work while we could direct them to Regaine®, a product that has trial evidence to support its use."

Nicola Osborne did not think that cost would be a barrier to sale. She commented: "Once pharmacists are confident in a product and know they are not misleading patients, they can pass this confidence on to their staff."

The Advisory Forum also noted that the heritage of Regaine® and the side-effect profile should help to give pharmacists confidence in recommending use of the foam.

There was agreement with Regaine® Foam placement as a lifestyle product. Peter Cattee said: "I believe it is useful to

see this product more as a part of male grooming." He also suggested that it could be useful to suggest that customers photograph their scalp so they can record progress to encourage continued use.

Samixa Shah thought that buying the triple pack should offer advantages over and above a financial saving. "Customers need added value and this is where pharmacy expertise comes in," she said. For example, pharmacists could encourage men to return for follow-up or might consider running hair loss clinics. "Pharmacy input can ensure users know that the treatment is not a quick fix," she said.

There are only a few products for male pattern hair loss available on the NHS and it was generally agreed that GPs are not interested in this problem. If Regaine® does not work and a customer wishes further advice, the Advisory Forum suggested that it might be appropriate to refer the customer to a trained trichologist.

In the UK, anyone can call themselves a trichologist but members of the Institute of Trichologists have undergone four years' training and adhere to a code of ethics. There are around 150 members and they are listed on Institute's website: [www.trichologists.org.uk](http://www.trichologists.org.uk).

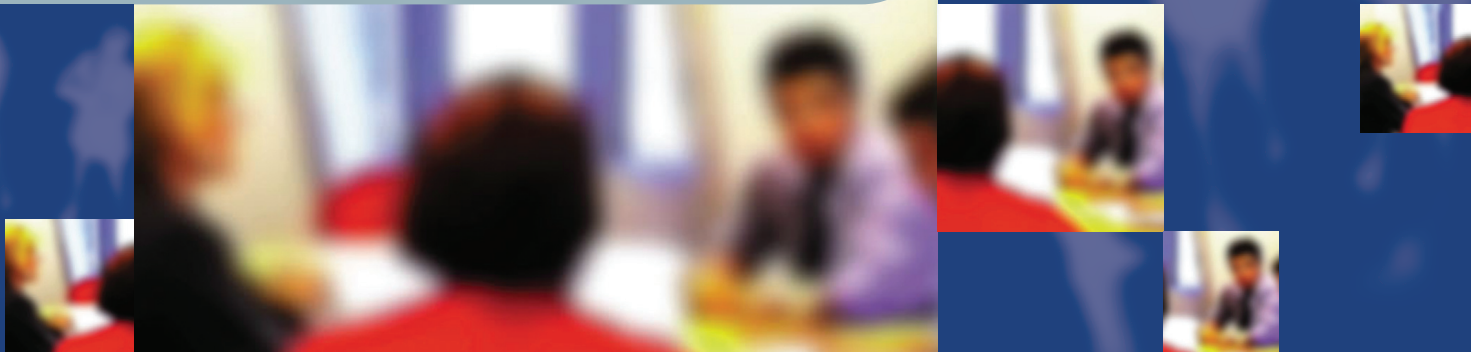


“ Once pharmacists are confident in a product and know they are not misleading patients, they can pass this confidence on to their staff. ”

## licensing of Regaine® products

- Regaine for Men Extra Strength Foam 5% (triple pack) P
- Regaine for Men Extra Strength Foam 5% (single pack) GSL
- Regaine for Men Extra Strength Solution 5% (triple pack) P
- Regaine for Men Extra Strength Solution 5% (single pack) GSL
- Regaine for Women Solution 2% (single pack) GSL

*Regaine for Men gel 2% and scalp solution 2% are discontinued*



PHARMACY MAGAZINE  
**advisory  
forum**

*Developed in partnership  
with McNeil,  
manufacturers of  
**Regaine®***

## did you know

- Transplanted hairs tend to maintain characteristics of the donor site. This is the basis of hair transplantation surgery: occipital hairs maintain their resistance to androgenetic alopecia when transplanted to the crown.<sup>1</sup>
- Androgens are thought to be associated with male pattern baldness. Eunuchs do not go bald.<sup>1</sup>

### WIDER SELF-CARE ISSUES

Self-care is a key part of Government health policy, with important implications for pharmacy, but young men are not typical pharmacy users. Could the new format help to encourage more self-care by this group?

“Self-care for men is very important and the availability of Flomax, and now Regaine® Foam, may help pharmacy to become more relevant to men,” Graham Phillips commented. He added: “While discussing these products, we could start discussing other issues around lifestyle. This is very exciting. We certainly do need

to think more broadly about making pharmacy appeal to men.”

Peter Cattee agreed, but thought it was a broader issue. “The issue with men is not just that they do not access pharmacy, they do not access healthcare in general. We really need a concerted effort involving the Department of Health and the medical profession.”

Members of the Advisory Forum also emphasised that pharmacists must embrace new products marketed for self-care or the industry will not continue to invest in new pharmacy products or product switches.

## Types of alopecia

**only androgenetic alopecia is suitable for treatment with OTC topical minoxidil**

Type	Description
Androgenetic alopecia	Male pattern baldness
Temporary alopecia	Hair is lost all over the scalp. Often caused by illness, stress or anticancer drugs
Alopecia areata	Bald patches appear suddenly and are usually caused by the body's immune system
Diffuse alopecia	Gradual thinning of hair, often caused by illness, iron deficiency, hormonal changes or anticancer drugs
Alopecia totalis	Total loss of all hair on head
Alopecia universalis	Total loss of all hair on head and body

**Regaine® For Men Extra Strength Scalp Foam 5% w/w Cutaneous Foam Product Information:** **Presentation:** Cutaneous foam containing Minoxidil 50mg/g (5% w/w). **Uses:** Treatment of alopecia androgenetica in men aged 18 to 49. **Dosage:** 1g twice daily to affected areas of scalp. Maximum dose 2g in 24 hours. **Contraindications:** Hypersensitivity to ingredients. Hypertension. Scalp abnormality. Shaved Scalp. Occlusive dressings on scalp or other topical medications. Also contraindicated for use in women. **Precautions:** For external use only on normal healthy scalp. Wash hands thoroughly after application. Avoid contact with eyes or sensitive surfaces. Stop use and see doctor if hypotension or other cardiovascular symptoms of systemic absorption develops. Patients with cardiovascular disease or arrhythmia to contact physician before use. **Interactions:** Topical drugs such as tretinoin, dithranol, betamethasone dipropionate. **Pregnancy and lactation:** Should not be used. **Side effects:** Headache, dyspnoea, pruritis, hypertrichosis, acneform rash, dermatitis, inflammatory skin disorder, musculoskeletal pain, peripheral oedema, depression, pain, hypertension. **RRP (ex-VAT):** Single pack- £29.74; Triple pack- £59.49 **Legal category:** Single Pack GSL; Triple Pack P **PL holder:** McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG **PL numbers:** Single Pack 15513/0366; Triple Pack 15513/0134 **Date of preparation:** December 2010.

Reference: 1) Sinclair R. Male pattern androgenetic alopecia. BMJ 1998;317:865-9. 2) Stearn M. Embarrassing Problems; Health Press 1998: 21-25. 3) Olsen EA, Whiting D, Bergfeld W, et al. A multicenter, randomized, placebo-controlled, double-blind clinical trial of a novel formulation of 5% minoxidil topical foam versus placebo in the treatment of androgenetic alopecia in men. J Am Acad Dermatol 2007;57:767-74.