

# Xamiol: betamethasone plus calcipotriol for scalp psoriasis

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## KEY POINTS

- Xamiol is a combined formulation of calcipotriol 50µg per g and betamethasone dipropionate 0.5mg per g in a gel formulation for the treatment of scalp psoriasis in adults
- recommended dose is 1-4g once daily
- in randomised trials lasting 8 weeks, Xamiol was superior to betamethasone, calcipotriol and vehicle alone in adults with moderate-to-severe scalp psoriasis of long duration; these differences were apparent after 2 weeks
- the proportions of patients rated with absent or very mild disease after 8 weeks were: Xamiol 71 per cent, betamethasone 64 per cent, calcipotriol 37 per cent and placebo 23 per cent
- Xamiol has not been compared with other treatments for scalp psoriasis
- it is as well tolerated as betamethasone and better tolerated than calcipotriol
- the commonest adverse effect is pruritus, though it is less frequent than with calcipotriol
- Xamiol offers a patient-friendly, once-daily formulation that is normally used overnight and so will facilitate adherence



**Xamiol, a new treatment for scalp psoriasis, is a formulation of betamethasone and calcipotriol in a gel vehicle. In this New products review Steve Chaplin discusses the clinical data relating to its efficacy and adverse effects and Dr Anthony Bewley comments on its place in the treatment of scalp psoriasis.**

Scalp psoriasis is common but can be difficult to treat. Guidance from the British Association of Dermatologists states: 'thick scale should be softened, by olive, coconut or arachis oil, ideally applied under occlusion (eg using a plastic shower cap or cling film), then removed using a detergent shampoo. This can be followed by applications of a coal tar, dithranol, or a topical steroid or vitamin D analogue preparation. Topical salicylic acid preparations, eg 2 per cent sali-

cyclic acid in a cream base such as Unguentum M, or coconut oil ointment (eg Cociois scalp ointment), can be used to remove thick scale from the scalp'.<sup>1</sup>

Another version of this guideline recommends initial treatment with a tar-based shampoo, combined with one or more of the alternative agents.<sup>2</sup>

There is a lack of comparative data on topical treatments for scalp psoriasis. Patients' dissatisfaction with treatment is reportedly high<sup>3</sup> and adherence to

topical treatments for psoriasis generally is said to be low.<sup>4</sup> However, in one study the adherence rate claimed by patients was 72 per cent,<sup>5</sup> and in another patients rated efficacy and safety above ease of application and non-greasiness as criteria for the ideal formulation.<sup>6</sup> One focus group study found a preference for foam and solution vehicles over a gel, cream or ointment.<sup>7</sup>

Currently available formulations specifically for scalp psoriasis include: vitamin D analogues,

eg calcipotriol scalp solution (Dovonex); tars, eg Coccois and Sebco scalp ointments and Psoriderm scalp lotion; dithranol, eg Psorin scalp gel; and corticosteroids.

**The technology**

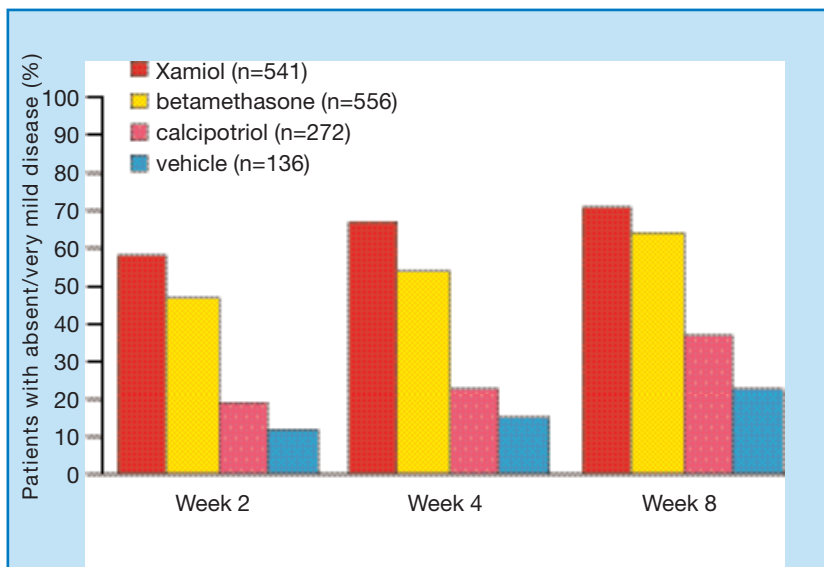
Xamiol is a clear and odourless gel containing calcipotriol 50µg per g and the potent steroid betamethasone dipropionate 0.5mg per g. It is licensed for the topical treatment of scalp psoriasis in adults at a recommended dose of 1-4g once daily (4g corresponds to one teaspoon), initially for four weeks before reviewing the need for repeat treatment. The gel should remain on the scalp during the night or during the day. If other products containing calcipotriol are used concurrently, the total dose of calcipotriol should not exceed 100g weekly or 15g daily.

Contraindications to Xamiol include disorders of calcium metabolism, active infection, open wounds, guttate, erythrodermic, exfoliative and pustular psoriasis, and skin atrophy.

**Clinical trials**

Xamiol has been compared with monotherapy with betamethasone or calcipotriol in three eight-week trials,<sup>8</sup> of which one has been published.<sup>9</sup> A 52-week double-blind safety trial included efficacy as a secondary end-point.<sup>10</sup>

The published trial<sup>9</sup> was a double-blind comparison of Xamiol with betamethasone, calcipotriol (both in the gel vehicle) or vehicle alone in 1505 adults, most of whom had moderate-to-severe psoriasis extending over up to half of the scalp with a mean duration of approximately 15-17 years. Other treatments were not allowed. The primary end-point



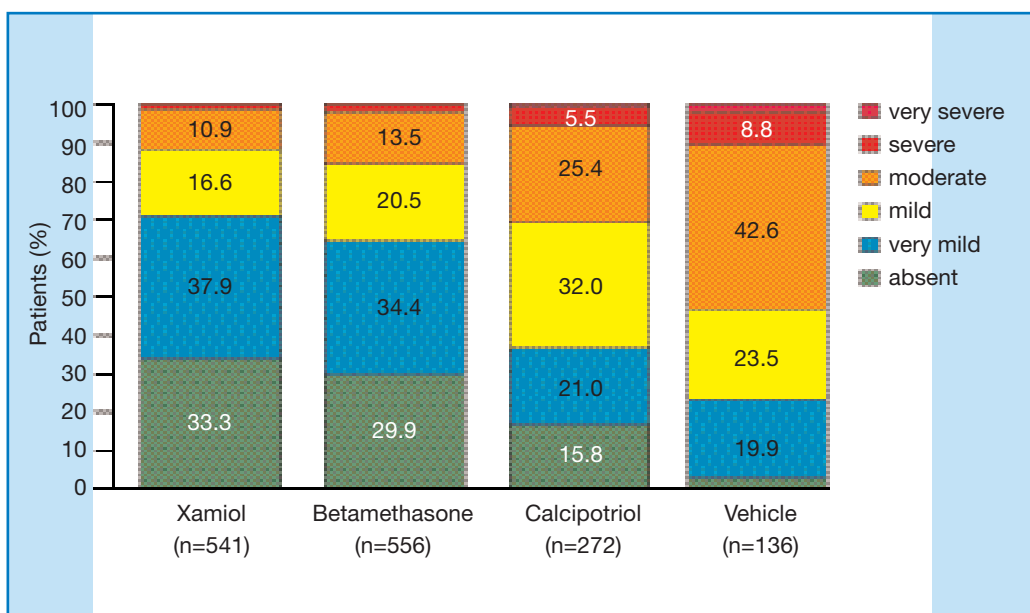
**Figure 1.** Physicians' global rating: proportions of patients with absent or very mild disease after two, four and eight weeks' treatment with Xamiol, betamethasone, calcipotriol or vehicle; all comparators significantly different to Xamiol ( $p < 0.05$ )<sup>9</sup>

was absent or very mild disease according to physicians' assessment at eight weeks. At baseline, 5-9 per cent of patients had mild disease.

Fewer patients discontinued treatment with Xamiol (11 per cent) or betamethasone (9 per cent) than calcipotriol (21 per

cent) or placebo (22 per cent). The difference was mainly due to lack of efficacy and adverse effects with calcipotriol.

Xamiol was significantly more effective than all comparators after eight weeks (71 per cent with absent or very mild disease vs betamethasone 64 per cent,



**Figure 2.** Distribution of disease severity by physicians' global assessment after eight weeks' treatment with Xamiol, betamethasone, calcipotriol or vehicle<sup>9</sup>

calcipotriol 37 per cent and placebo 23 per cent) and at other time points (see Figure 1). Patients' assessments of treatment response were similar.

Scores of redness, plaque thickness and scaliness improved equally with Xamiol and betamethasone, and significantly more than with calcipotriol or placebo.

The distribution of disease severity at eight weeks is illustrated in Figure 2.

Analysis of data pooled from this and a large unpublished trial produced similar results.<sup>8</sup> An unpublished trial in 312 patients with moderately severe scalp psoriasis compared Xamiol once daily with calcipotriol scalp solution twice daily; after eight weeks, the proportions of patients with absent or very mild disease were 69 and 31 per cent respectively.<sup>8</sup>

In the one-year study,<sup>10</sup> 869 patients with scalp psoriasis of at least moderate severity affecting at least 10 per cent of the scalp were randomised to treatment with Xamiol or calcipotriol 50µg per g in the same vehicle. Other topical scalp treatments and systemic treatments were not allowed. The primary end-point was the incidence of adverse effects (see below). Secondary end-points were efficacy according to physicians' global assessment and patients' ratings. The mean duration of psoriasis was 17-18 years. The distribution of severity at baseline was moderate 56 per cent, severe 38 per cent, and very severe 7 per cent.

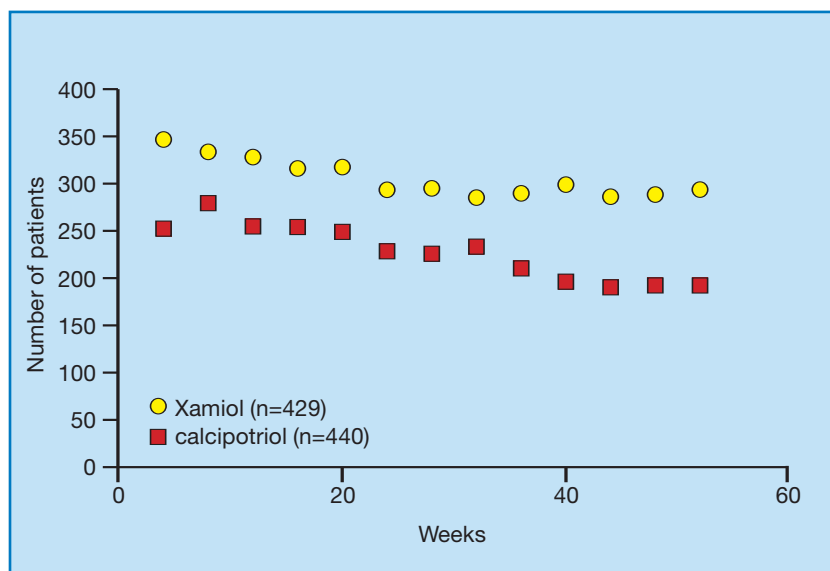
Twenty-one per cent of patients discontinued Xamiol prematurely compared with 40 per cent assigned to calcipotriol. The main differences were due to a higher

incidence of unacceptable adverse effects (10 *vs* 2 per cent) and lack of efficacy (12 *vs* 3 per cent) with calcipotriol.

The mean duration of treatment was 44 weeks for Xamiol and 37 weeks for calcipotriol. Xamiol was associated with more patients achieving satisfactory control (absence of, very mild or mild psoriasis) than calcipotriol by physicians' rating throughout the trial (see Figure 3). The proportions of patients rating the response as satisfactory at all of the four-weekly assessment visits were 76 per cent with Xamiol and 50 per cent with calcipotriol ( $p<0.001$ ).

### Adverse effects

The most frequent reaction reported in clinical trials is pruritus, occurring in 4 per cent of patients overall compared with 10 per cent with calcipotriol.<sup>10</sup>



**Figure 3.** Physicians' global rating of response to treatment with Xamiol and calcipotriol over one year: number of patients with absence of, very mild or mild psoriasis<sup>10</sup>

Uncommon adverse reactions include burning sensation, skin pain or irritation, folliculitis, dermatitis, erythema, acne, dry skin, exacerbation of psoriasis, rash, pustular rash and eye irritation.<sup>8</sup>

The frequency of these adverse reactions does not appear to increase with treatment for up to one year.<sup>10</sup>

#### References

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## Place in therapy

Xamiol is a new combination preparation, a mixture of beta-methasone dipropionate and calcipotriol in a novel gel vehicle, for scalp psoriasis. Prior to the development of Xamiol, patients with scalp psoriasis were obliged to use several, often quite messy, topical preparations to treat their scalp disease.

Xamiol is a fast acting (large clinical improvements reported in two weeks) once-daily topical gel, normally used overnight, and so will facilitate patient acceptability and adherence. The novel vehicle is a nonodorous, silky gel that maintains stability

of both active ingredients and that has an additional emollient action.

Xamiol is applied to the scalp via repeated parting of the hair and application of the product to the exposed scalp skin. The patient starts at one side of the head, parting and applying the preparation, and then moves to the immediately adjacent scalp and repeats the process until all the affected scalp skin has been treated. This usually takes a few minutes.

The treatment is left on overnight and removed the following morning by applying shampoo a few minutes before wetting the hair in the shower or wash-basin.

It is best if the process is repeated on a nightly basis until the scalp psoriasis is in remission; this usually takes only a few weeks. If there is a recurrence of the psoriasis, Xamiol can be applied on an as-required basis under medical supervision.

In research Xamiol has been found to be a very safe, fast-acting, well-tolerated and effective treatment. In addition to this it is a patient-friendly and once-daily treatment that patients have found very easy to use.

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