SAFERx®
SAFER USE OF HIGH RISK MEDICINES

Waitemata District Health Board
Te Wai Awhina

IMIQUIMOD (ALDARA®) - SAFE PRESCRIBING - A BURNING ISSUE

- TOPICAL IMIQUIMOD SHOULD BE USED WITH SPECIAL CARE
- INCORRECT USE MAY CAUSE PATIENT HARM
- LOCAL SKIN REACTIONS ARE COMMON; SYSTEMIC REACTIONS ALSO OCCUR
- PRESCRIBE AND DISPENSE CAREFULLY
- ENSURE PATIENTS UNDERSTAND HOW TO USE IT; REVIEW REGULARLY

Imiquimod cream (Aldara®) is unlike most other topical treatments and special care is required for it to be used safely[1]. Imiquimod is considered to be a *high-risk* medicine because there is potential for harm even when it's used correctly[2]. There have been reports of significant side-effects, both at the site of application and systemically[3].

Problems may arise because it has a different dosing regimen compared to most other topical products (i.e. it is not used everyday)[1]; its frequency of use also depends on the indication for which it's being prescribed (e.g. genital warts vs. superficial basal cell carcinoma)[2]. Compared to many other topical medicines, imiquimod cream may be less convenient to use, and extra care is required when applying[1].

Imiquimod therapy requires patients to persevere with a six week course, often through a degree of treatment-related discomfort[1]. Its use has been associated with a number of adverse reaction reports (local and systemic – see below[2]). Occasionally, the local reactions may necessitate a 'rest period'[2]; systemic reactions can sometimes be relieved with oral paracetamol[4].

Harm may occur as a consequence of incorrect use[1]. In 2 cases reported to CARM, the patients had used the cream more frequently than recommended and developed ulceration at the site of application[3]. There have also been reports of patients with toxicity after adhering to incorrect dosing instructions following prescribing and/or dispensing errors (i.e. labelled 'three times a day', instead of 'three times a week')[5].

Local inflammatory reactions can occur at any time during treatment and they can often be troublesome[1]. They commonly include: oedema, erosion, redness, flaking/scaling, thickening/hardening, and scabbing/crusting[1,2]. In trials, more than 50% of patients had these reactions, and about 1% had an infection at the application site. Skin irritations are also common: 16% having itch, 7% burning, and 3% pain[6].

Cases of hyper- and hypopigmentation at the site of application have been reported; some of these skin colour changes can be permanent[2]. In one trial, using imiquimod 3 times a week for up to 12 weeks, 31% of patients had pigment changes that persisted at 6 months after treatment[7]. Imiquimod may also cause generalised exacerbations of pre-existing eczema and psoriasis[1].

Systemic side-effects such as fatigue, headache, and flu-like illnesses have been reported[2,3], although only a small percentage of topical imiquimod is absorbed into the circulation[6]. In trials, symptoms included: headache (8% of patients), lymphadenopathy (2%), fatigue (2%), and fever (2%)[1]. There have been case reports of more serious events; these may be due to increased absorption through inflamed or vascular skin (e.g. scalp)[8].

Toxicity from incorrect imiquimod use may be prevented by:

- Carefully prescribing and checking the frequency, and labelling correctly when dispensing
- Choosing imiquimod only for patients who you know will use it correctly[1]
- Warning patients about the expected adverse reactions - and how to deal with them[1,4]
- Scheduling regular reviews (e.g. 2-weekly) for on-going treatment to promote adherence, treat side-effects, and manage treatment 'rest periods'/adjust dosing intervals[1].

➥ continued

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IMIQUIMOD (ALDARA®)

ALDARA® GENERAL INFORMATION

- Before applying, patients should wash the treatment area and dry thoroughly
- The cream should be applied prior to sleep and remain on the skin for 8 (6-10) hours; avoid bathing/showering during this period
- Rub with fingertip into affected area until cream vanishes
- Wash area with soap and water at end of treatment period
- A single use sachet is sufficient to cover an area of 20cm^2

Please refer to full information in Aldara® datasheet before prescribing[6]

Indication	Dose	Comment
Actinic keratosis	Three times a week	▸ Max dose = 1 sachet ▸ Review after 4 weeks; repeat if necessary ▸ Max treatment duration 8 weeks
Superficial basal cell carcinoma	Once daily for 5 consecutive days per week	▸ Apply to tumour and 1 cm of surrounding skin ▸ Continue treatment for 6 weeks ▸ Review 6-12 weeks after end of treatment
External genital/perianal warts	Once daily, 3 times a week (every other day followed by a 2 day treatment-free interval)	▸ Continue until wart clearance, or a max of 16 weeks ▸ Apply after, rather than before sexual activity

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