



PRODUCT PIPELINE

New Product Elidel (pimecrolimus 1% cream)

Health Canada has approved pimecrolimus 1% cream for the short-term and intermittent long-term therapy of mild-to-moderate atopic dermatitis in non-immunocompromized patients aged ≥ 2 years. The product is suitable for use in those in whom the use of alternative, conventional therapies is inadvisable because of potential risks, or in those who are unresponsive to, or intolerant to, conventional therapies.¹

The product monograph does not explicitly state what is meant by “alternative therapies” — presumably this is an oblique reference to topical corticosteroids.¹

Pimecrolimus is an ascomycin macrolactam derivative that inhibits T-cell activation by blocking transcription of cytokines. The drug also inhibits release of cytokines and pro-inflammatory cytokines from mast cells.¹

Pimecrolimus was more effective than “conventional treatment” for atopic dermatitis in 713 pediatric patients aged two to 17 years in a one-year, randomized, double-blind trial. Significantly fewer recipients of pimecrolimus than conventional therapy experienced flares of atopic dermatitis during the study (50.8% vs 28.3% after 12 months). Investigators were allowed to prescribe topical corticosteroids to manage the condition at their discretion. The incidence of corticosteroid use was significantly lower in pimecrolimus recipients (42.6% vs 68.4% in recipients of conventional therapy after 12 months). The discontinuation rate was also significantly lower in the pimecrolimus group (31.6% vs 51.5%).²

Pimecrolimus has also been studied in infants with atopic dermatitis³ although the product is not approved for use in children aged < 2 years.¹

After topical administration, systemic absorption of pimecrolimus is minimal (i.e., maximum blood concentrations < 2 ng/ml in adults).¹

Although systemic exposure to pimecrolimus is low after topical application, and the drug is not teratogenic in animals, the safety of the drug when used during pregnancy or breast feeding is unknown and the manufacturer advises that pimecrolimus be used only if clearly needed in such situations.¹

The most common adverse effect of pimecrolimus 1% cream is a burning feeling or a sensation of warmth at the site of application.¹

Pimecrolimus 1% cream is applied to affected areas twice daily and may be used on all skin surfaces including the head, neck and intertriginous areas. The manufacturer recommends that treatment be continued as long as symptoms persist and, conversely, should be discontinued if resolution of the disease occurs. Should no improvement occur after three weeks of treatment, or in the event of an exacerbation during ongoing therapy, treatment with pimecrolimus should be discontinued.¹

Recent Product Approvals in Canada	
PRODUCT & MANUFACTURER	COMMENT
New indications¹	
Advair Diskus (salmeterol/fluticasone) GlaxoSmithKline	Maintenance treatment of COPD
Effexor, Effexor XR (venlafaxine) Wyeth	Maintenance treatment of major depressive disorder
Valtrex (valacyclovir)	Treatment of cold sores (herpes labialis)
New vaccines^{2,3}	
Dukoral, Aventis Pasteur	Two dose oral vaccine for traveller's diarrhea
Varivax III (live attenuated varicella vaccine), Merck Frosst	Two subcutaneous doses for immunization against chickenpox
Sources (Accessed 21 May 2003): 1. http://www.hc-sc.ca/hpfb-dgpsa/tpd-dpt/noc/2003/pre2003et.txt 2. http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/noc/2003/bio2003et.txt 3. http://www.docguide.com	

Pimecrolimus is stable at room temperature and may be kept for up to 12 weeks after piercing the tube. Elidel is marketed in Canada by Novartis.¹

1. Elidel (pimecrolimus cream, 1%) product monograph. Novartis Pharmaceuticals Canada Inc. Dorval, PQ, March 10, 2003
2. Wahn U, Bos JD, Goodfield M et al. Efficacy and safety of pimecrolimus cream in the long-term management of atopic dermatitis in children. *Pediatrics* 110 No. 1, July 2002 (Available at <http://www.pediatrics.org/cgi/content/full/110/1/e2> accessed 21 May, 2003)
3. Ho VC, Gupta A, Kaufmann R, et al. Safety and efficacy of nonsteroid pimecrolimus cream 1% in the treatment of atopic dermatitis in infants. *J Pediatr* 2003 142: 155-62

Avandamet (combination rosiglitazone/metformin)

Health Canada has approved a combination of rosiglitazone and metformin for use as an adjunct to diet and exercise to reduce insulin resistance and improve glycemic control in patients with type 2 diabetes mellitus. The combination is indicated when diet, exercise, and metformin or rosiglitazone do not adequately control blood sugar levels.¹

The manufacturer advises that the combination should be administered in divided doses with meals (as with metformin monotherapy) with gradual dose escalation.

1. Avandamet (rosiglitazone maleate/metformin hydrochloride tablets) Product Monograph. GlaxoSmithKline Inc. Mississauga, ON. 21 January 2003.