Review Am J Clin Dermatol. 2003;4(3):203-13. doi: 10.2165/00128071-200304030-00007.

Topical 3% diclofenac in 2.5% hyaluronic acid gel: a review of its use in patients with actinic keratoses

Blair Jarvis [1], David P Figgitt

Affiliations

PMID: 12627996 DOI: 10.2165/00128071-200304030-00007

Abstract

Topical 3% diclofenac in 2.5% hyaluronic acid (HA) gel (diclofenac HA gel; Solaraze) is an NSAID approved for the treatment of actinic keratoses (AK). The efficacy of diclofenac HA gel (0.5g applied twice daily to each 5cm x 5cm treatment area) in patients with AK has been evaluated in three randomized, double-blind, HA gel vehicle-controlled trials. In each trial, efficacy was assessed 30 days after the end of treatment because an earlier study revealed that resolution of lesions was greater when measured after a 4 week interval, rather than at the end of treatment. In two fully published multicenter trials, there was no difference in baseline characteristics of the study groups. In a further single center study (not yet published), patients randomized to diclofenac HA gel had a significantly higher mean number of target lesions at baseline compared with HA gel vehicle. In the two published studies, the efficacy of diclofenac HA gel increased with increased treatment duration. When compared with HA gel vehicle recipients, significant improvements in total lesion number scores (TLNS), cumulative lesion number scores (CLNS), patient global improvement indices (PGII) and investigator global improvement indices (IGII) were obtained in patients treated for 60 and 90 but not 30 days with diclofenac HA gel. Fifty percent of patients treated for 90 days with diclofenac HA gel (vs 20% in HA gel vehicle recipients) and 33% of those treated for 60 days (vs 10%) had TLNS and CLNS of zero at the end of follow-up. In the third trial, in which treatment was applied for 90 days, there was no statistically significant difference in the proportion of patients with TLNS or CLNS of zero at the end of follow-up. However, when controlling for the significant difference in mean baseline target lesion scores by calculating the mean change from baseline in lesion counts, TLNS and CLNS were significantly lower in recipients of diclofenac HA gel than HA gel vehicle at the end of follow-up. Pruritus was the most frequently reported adverse event in all trials and the incidence was generally similar or lower in patients treated with diclofenac HA gel than HA gel vehicle. In conclusion, diclofenac HA gel produces significant reductions in the number of AK lesions, and can produce complete clearance of lesions when applied twice daily for 60 or 90 days. The product is well tolerated and did not produce serious adverse cosmetic effects in clinical trials. Thus, diclofenac HA gel represents a useful addition to the array of pharmacologic treatments available for AK.

Related information

PubChem Compound

PubChem Compound (MeSH Keyword)
PubChem Substance

LinkOut - more resources

Full Text Sources
Ovid Technologies, Inc.
Springer

Other Literature Sources
The Lens - Patent Citations