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## (57) Abstract:

The present invention discloses a novel dosage form for use as a topical/cutaneous analgesic wherein the same consists of the drug midazolam along with suitable excipients for formulating as cream, ointment, lotion or dermal spray. Known therapeutic use of Midazolam is as an anti-anxiety drug (oral) and as an anesthetic (injectable) but not as an analgesic. The inventors evaluated existing compounds for therapeutic potential as a topical analgesic free from side-effects. Surprisingly, Midazolam not only emerged as a good candidate with strong analgesic effect when used topically but was also free from any undesirable side-effects. It has very low Primary Irritation Index (PII <2) i.e. it is non-irritating. Further, it did not exert any significant change in the locomotor activity. Effective dosage in test subjects (rats) was found to be 30 mM for topical application and the equivalent dose in humans being was about 1.5 grams per kg body weight.

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