Emerging Drug List
Topical Diclofenac Sodium

Canadian Coordinating Office for Health Technology Assessment

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Generic (Trade Name): **Topical Diclofenac Sodium** (Pennsaid®)

Manufacturer: Dimethaid Research

Indication: For the topical treatment of pain associated with osteoarthritis

Current Regulatory Status: The company has submitted Pennsaid® for review by Health Canada and is expecting a notice of compliance during the summer of 2001. Marketing is planned for the fall of 2001.

Description: Pennsaid® contains 1.5% diclofenac in a 45% dimethyl sulfoxide (DMSO) base. It is available in bottles of 60 mL. Diclofenac is a nonsteroidal anti-inflammatory agent (NSAID) that has been available in Canada for several years in an oral dosage form for the treatment of pain associated with arthritis. Topical NSAIDs have been available for many years in Europe, but Pennsaid® will be the first topical NSAID to be marketed in Canada.

Current Treatments: Currently, treatment for pain associated with osteoarthritis includes oral acetaminophen and NSAIDs. Topical preparations containing salicylates (i.e. triethanolamine salicylate, methyl salicylate, diethylamine salicylate), capsaicin, eucalyptus oil, or chloroxylenol are currently available in Canada without a prescription for the treatment of local pain associated with arthritis, bursitis, tendonitis, backache, strains, and sprains.

Topical diclofenac will most likely be indicated for pain relief associated with osteoarthritis, hence the manufacturer will most likely be marketing its use as an alternative to oral acetaminophen and oral NSAIDs.

Cost: The cost of Pennsaid® during trials was $45.00 for a 60 mL bottle. Presently, the company plans to sell Pennsaid® at the same cost once it is marketed.

Evidence: There is very limited published data with topical diclofenac. Of the studies available, none used the Pennsaid® formulation (i.e. 1.5% diclofenac in 45% DMSO). There exists non-comparative trials with a 2% diclofenac in organogel, 3% diclofenac in a 2.5% hyaluronan gel, and comparative trials with an emulsion diclofenac gel (concentration not specified). Hence, evidence on the usefulness of Pennsaid® cannot be discussed here. The comparative trials compared diclofenac to topical indomethacin in 64 patients with back pain and to topical biphenyl acetic acid in 40 patients with osteoarthritis. There was no difference in pain, functional, or patient ratings between the agents. Topical diclofenac has not been compared to any oral

Adverse Effects: NSAID, hence its place in therapy compared to NSAIDs cannot be discussed at this time.

Conclusion: Local adverse effects of topical NSAIDs include itching, rashes, erythema, and eczema (usually in the range of 1-4%). Systemic effects including gastrointestinal effects, asthma, and renal impairment have been rarely reported. Studies focusing on long term adverse effects associated with topical diclofenac are lacking.

References: Pennsaid® will be the first topical NSAID to be marketed in Canada for the treatment of osteoarthritis. Scientific data in the form of comparative clinical trials needs to be made available so that its place in therapy can be assessed.

1. Heyneman CA, Lawless-Liday C, Wall GC. Oral versus topical NSAIDs in rheumatic disease: a comparison. Drugs 2000;60(3):555-74.
2. Anon. Topical NSAIDs for joint disease. Drug and Therapeutics Bulletin 1999;37(11):87-8.
3. Anon. Topical NSAIDs may be useful for treating soft tissue injuries. Drugs & Therapy Perspectives 1999;13(12):11-3.
4. Heyneman CA, Lawless-Liday C, Wall GC. Oral versus topical NSAIDs in rheumatic diseases: A Comparison. Drugs 2000;60(3):555-74.
5. Personal communication with Renny Ho, Director, Investor Relations, Dimethaid Research, 905-415-1446.

The contents of this bulletin are current as of April 2001.
The Emerging Drug List highlights drugs not yet approved in Canada that are anticipated to have a significant impact on the health care system. Minimal information is available about these drugs, and they may in future become the subject of an early assessment.

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