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Denavir (Penciclovir)

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Clinical Studies

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In two double-blind, placebo-controlled trials, 1516 patients were treated with DENAVIR (penciclovir cream) and 1541 with placebo. One or more local adverse reactions were reported by 3% of the patients treated with DENAVIR and 4% of placebo-treated patients. The rates of reported local adverse reactions are shown in Table 1.

Table 1 : Local Adverse Reactions Reported in Phase III Trials

Placebo N=1541 %	Penciclovir n=1516 %	
2	1	Application site reaction
< 1	< 1	Hypesthesia/Local anesthesia
< 1	< 1	Taste perversion
< 1	< 1	Rash (erythematous)

Two studies, enrolling 108 healthy subjects, were conducted to evaluate the dermal tolerance of 5% penciclovir cream (a 5-fold higher concentration than the commercial formulation) compared to vehicle using repeated occluded patch testing methodology. The 5% penciclovir cream induced mild erythema in approximately one-half of the subjects exposed, an irritancy profile similar to the vehicle control in terms of severity and proportion of subjects with a response. No evidence of sensitization was observed.

Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of DENAVIR. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following events have been identified from worldwide post-marketing use of DENAVIR in treatment of recurrent herpes labialis (cold sores) in adults. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to DENAVIR.

Headache, oral/pharyngeal edema, parosmia. **General:**

Aggravated condition, decreased therapeutic response, local edema, pain, paresthesia, pruritus, skin discoloration, and urticaria. **Skin:**