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DOSAGE AND ADMINISTRATION

For Proposed Hydrocodone Bitartrate and Ketoprofen Tablets, 7.5 mg/12.5 mg

For the short-term (generally less than 10 days) management of acute pain, the recommended dose is one tablet every 4 to 6 hours, as necessary. Dosage should not exceed 5 tablets in a 24-hour period. It should be kept in mind that tolerance to hydrocodone can develop with continued use and that the incidence of untoward effects is dose related.

The lowest effective dose or the longest dosing interval should be sought for each patient, especially in the elderly. After observing the initial response to therapy with the drug product, the dose and frequency of dosing should be adjusted to suit the individual patient's need, without exceeding the total daily dose recommended.