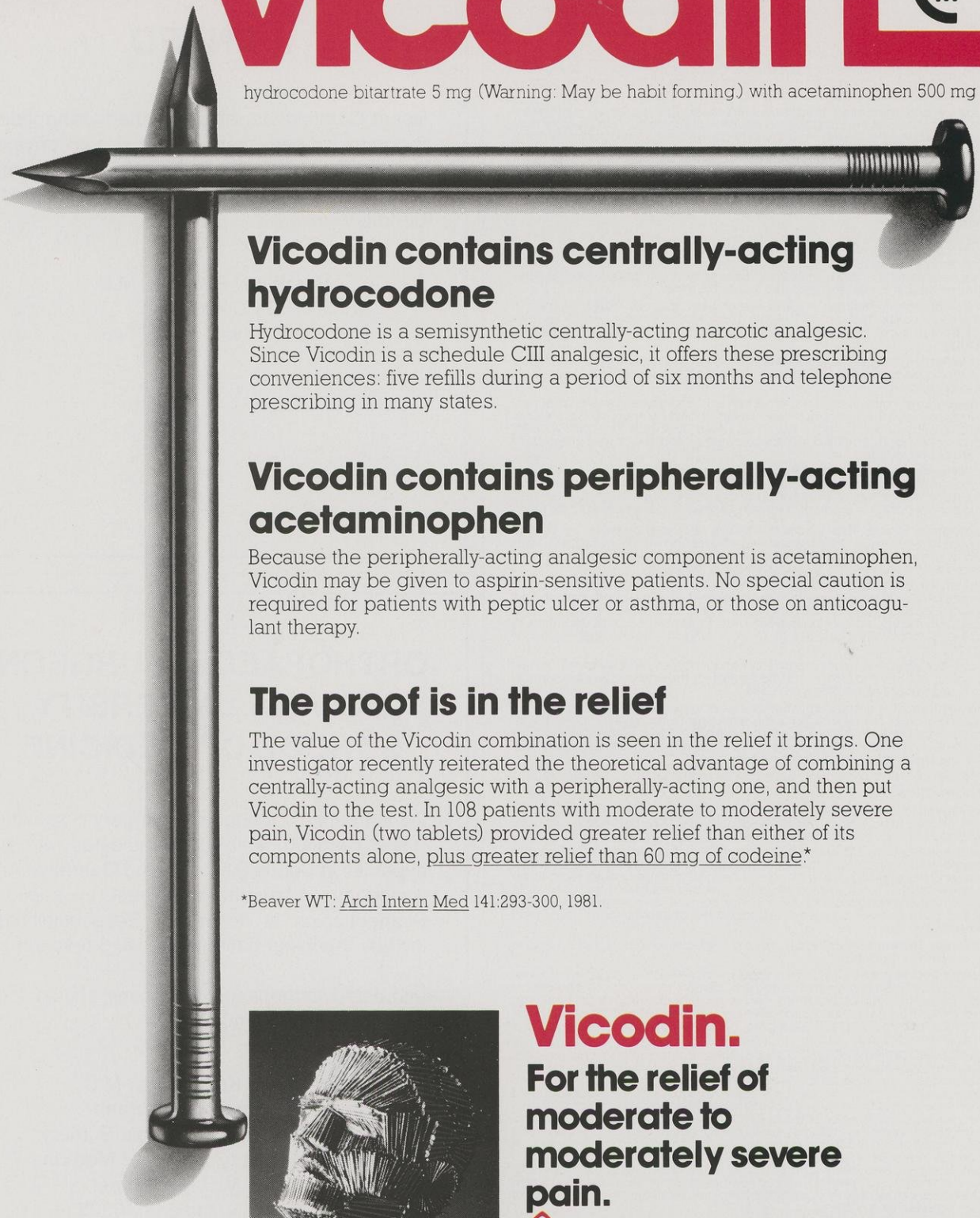
Vicodin advertisement.

[s.l.]: [s.n.], 1978

https://digital.library.wisc.edu/1711.dl/F47WDEEQSZHZK8Y

vicodin® CIII

hydrocodone bitartrate 5 mg (Warning: May be habit forming.) with acetaminophen 500 mg



Vicodin contains centrally-acting hydrocodone

Hydrocodone is a semisynthetic centrally-acting narcotic analgesic. Since Vicodin is a schedule CIII analgesic, it offers these prescribing conveniences: five refills during a period of six months and telephone prescribing in many states.

Vicodin contains peripherally-acting acetaminophen

Because the peripherally-acting analgesic component is acetaminophen, Vicodin may be given to aspirin-sensitive patients. No special caution is required for patients with peptic ulcer or asthma, or those on anticoagulant therapy.

The proof is in the relief

The value of the Vicodin combination is seen in the relief it brings. One investigator recently reiterated the theoretical advantage of combining a centrally-acting analgesic with a peripherally-acting one, and then put Vicodin to the test. In 108 patients with moderate to moderately severe pain, Vicodin (two tablets) provided greater relief than either of its components alone, plus greater relief than 60 mg of codeine.*

*Beaver WT: Arch Intern Med 141:293-300, 1981.

Vicodin.

For the relief of moderate to moderately severe pain.

knoll® **KNOLL PHARMACEUTICAL COMPANY**
30 NORTH JEFFERSON ROAD, WHIPPANY, NEW JERSEY 07981

Please see following page for brief summary of prescribing information.

5672

BRIEF SUMMARY

vicodin® III

hydrocodone bitartrate* 5 mg with acetaminophen 500 mg
*Warning: May be habit forming.

INDICATIONS AND USAGE: For the relief of moderate to moderately severe pain.

CONTRAINDICATIONS: Hypersensitivity to hydrocodone or acetaminophen; intracranial lesion associated with increased intracranial pressure; status asthmaticus; liver disease.

WARNINGS:

Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on brain stem respiratory centers. Hydrocodone also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing.

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

PRECAUTIONS:

Special Risk Patients: As with any narcotic analgesic agent, VICODIN should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.

Usage in Ambulatory Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when VICODIN is used postoperatively and in patients with pulmonary disease.

Drug Interactions: Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics or other CNS depressants (including alcohol) concomitantly with VICODIN may exhibit an additive CNS depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.

Usage in Pregnancy: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever.

The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose. There is no consensus on the best method of managing withdrawal. Chlorpromazine 0.7 to 1.0 mg/kg q6h, phenobarbital 2 mg/kg q6h, and paregoric 2 to 4 drops/kg q4h, have been used to treat withdrawal symptoms in infants. The duration of therapy is 4 to 28 days, with the dosage decreased as tolerated.

Labor and Delivery: As with all narcotics, administration of VICODIN to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from VICODIN, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.

Gastrointestinal System: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. The antiemetic phenothiazines are useful in suppressing these effects; however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of VICODIN may produce constipation.

Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.

Respiratory Depression: VICODIN may produce dose-related respiratory depression by acting directly on brain stem respiratory centers. Hydrocodone also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride, 0.005 mg/kg intravenously. Apply other supportive measures when indicated.

DRUG ABUSE AND DEPENDENCE: VICODIN is a Schedule III narcotic. Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, VICODIN should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when VICODIN is used for a short time for the treatment of pain. Physical dependence, the condition in which continued administration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued narcotic use, although some mild degree of physical dependence may develop after a few days of narcotic therapy. Tolerance, in which increasingly large doses are required in order to produce the same degree of analgesia, is manifested initially by a shortened duration of analgesic effect, and subsequently by decreases in the intensity of analgesia. The rate of development of tolerance varies among patients.

DOSAGE AND ADMINISTRATION: VICODIN is given orally. The usual adult dose is one tablet every 6 hours as needed for pain. In cases of more severe pain, two tablets every 6 hours or one tablet more frequently than every 6 hours (up to 8 tablets in 24 hours) may be required.

5662 4/80

5672

knoll®
KNOLL PHARMACEUTICAL COMPANY
30 NORTH JEFFERSON ROAD, WHIPPANY, NEW JERSEY 07981