

Within the past four years the Federal Food and Drug Administration, which is charged with approving—or disapproving—new prescription drug applications, has tightened the requirements leading to a new prescription drug being permitted on the market. Indocin has passed these new, much tougher standards.

Despite this, Indocin *does* have side effects—at least for some patients. And some patients get little if any therapeutic effect from the drug.

Here, in brief, is a rundown on the “minus” side of the Indocin ledger: Somewhere between ten and 25 per cent of the patients experience side effects. Some of these are mild, some are severe. Some patients experience headache, nausea, dizziness, and a few have intestinal bleeding. However, it is estimated that these effects are mild much of the time. Only an estimated ten to 15 per cent of the patients must give up the drug because of negative effects.

Says the Council on Drugs of the American Medical Association in a report not yet published: “With prolonged administration, ten per cent to 15 per cent of the patients who responded initially must stop taking indomethacin because of its untoward effects. . . .”

However, also within the AMA report, the following appears: “Indomethacin has been particularly useful in the treatment of . . . osteoarthritis of hip joint, a condition that is resistant to all other anti-inflammatory agents. . . .”

“Indomethacin produces anti-inflammatory effects in patients with gout. . . . It has produced relief in acute attacks within 48 hours.

“Because it lacks the untoward effects of colchicine [another anti-gout drug], some clinicians consider it to be the drug of choice for these attacks. . . .”

One of the most striking talents of Indocin lies in its ability to go to work quickly on the painful joint. Animal and human tests have shown that once Indocin is given, it reaches peak levels in the blood in just 30 minutes to two hours.

Thus, certain patients have begun to note relief from joint aches in two, three, six, or ten hours. One bursitis patient, for example, a 35-year-old executive from Hartsdale, New York, told his family doctor that once he took Indocin, “My shoulder began to feel better in just two or three hours. On just two Indocin capsules per day, I can feel pretty comfortable during an acute bursitis attack.”

A random sampling of a half-dozen doctors in various medical centers around the country produced the following assessments of Indocin:

1. When the drug works in a patient, the results are very dramatic. Relief comes quickly and may last for long periods.
2. In some patients, however, there are no beneficial effects at first. The drug must be continued for some weeks before it does any good at all.
3. Patients on Indocin should be watched very carefully for side effects. It has been reported that, following Indocin administration, some individuals have developed ulcers. However, it cannot be stated categorically that the drug had anything to do with the onset of this stomach ailment.
4. Somewhere around 75 to 80 per cent of all patients tolerate the drug well—and most of these patients experience real relief from symptoms.
5. Apparently, results are most remarkable among patients with arthritis of the hip, but many other patients with joint ailments do get dramatic relief in comparatively short periods.

Actually, the first human trials with Indocin started in November 1961. Since that time, more than 5,000 patients have been involved in worldwide studies of Indocin. Prior to the “patient-testing stage” more than 100,000 animal experiments were conducted by Merck to establish that the drug was potent and had worthwhile effects.

In those animal studies it was found that if researchers injected animals with a drug that itself could cause considerable inflammation, Indocin could reverse the inflammatory effects.

As is the case of so many other drugs, the exact mode of action of Indocin is not known. The same holds true for aspirin—the most widely used of all medications—and for penicillin—the miracle drug that has saved more lives than perhaps any other drug in the history of man. Doctors know that aspirin and penicillin work but are not exactly sure how they work. This is true, too, of Indocin.

Once it was established that Indocin could reduce inflammation, further tests indicated that its site of action must be within the inflamed joint itself. In addition, tests showed that its anti-pain capabilities at least equaled those of aspirin (which also is widely prescribed for arthritis) and in some instances exceeded the results aspirin could produce.