PRECAUTIONS AND ADVERSE REACTIONS

The most frequent adverse reactions associated with INDOCIN are headache, dizziness, lightheadedness, and gastrointestinal disturbances such as nausea, anorexia, vomiting, epigastric distress, abdominal pain or diarrhea. The central nervous system effects are often transient and frequently disappear with continued treatment or with a reduction of dosage. The severity of these effects may, on occasion, require stopping therapy.

The gastrointestinal effects may be minimized by giving the drug immediately after meals or with food.

Studies in normal subjects with radioactive chromate-tagged red blood cells indicate that large doses of indomethacin (50 mg. four times a day) produce less fecal blood loss than average doses of aspirin (600 mg. four times a day). Notwithstanding, INDOCIN may cause single or multiple ulceration of the stomach, duodenum, or small intestine. There have been reports of severe bleeding and of perforation with a few fatalities. Patients may also develop gastrointestinal bleeding with no obvious ulcer formation. If gastrointestinal bleeding occurs, INDOCIN should be discontinued. In many patients with peptic ulceration a history of a

INDOCIN®
(indomethacin)

previous ulcer was present or they were on concomitant steroids, salicylates, or phenylbutazone. The possible potentiation of the ulcerogenic effect of these drugs cannot be ruled out at present. In some patients there was no history of a previous ulcer and other drugs were not being given. As a result of obvious or occult gastrointestinal bleeding some patients may manifest anemia. For this reason periodic hemoglobin determinations are recommended.

Rare reports where it is not known whether the effects can be attributed to the drug include bleeding from the sigmoid colon, either from a diverticulum or without a known previous pathologic condition, and perforation of pre-existing sigmoid lesions (diverticulum, carcinoma). In other rare cases a diagnosis of gastritis has been made while INDOCIN was being given. One patient developed ulcerative colitis and another regional ileitis while receiving INDOCIN. When INDOCIN was given to patients with pre-existing ulcerative colitis, there was an increase in abdominal pain.

Other adverse effects that have been infrequently reported include drowsiness, tinnitus, mental confusion, depression and other psychic disturbances, blurred vision, stoma-