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INDOCIN®

(INDOMETHACIN)



INDOCIN® (indomethacin) is a new "anti-rheumatic" drug that has anti-inflammatory, analgesic, and antipyretic activity. It has a unique chemical structure which differentiates it from the salicylates, corticosteroids, phenylbutazone-like compounds, and colchicine. Unlike corticosteroids, it has no effect on pituitary or adrenal function.

INDOCIN is an effective anti-inflammatory agent that is suitable for long term as well as short term use in adult patients of all ages. It has been found effective to relieve pain; reduce fever, swelling, and tenderness; and increase mobility in patients with rheumatic disorders.

INDICATIONS

INDOCIN has been found effective in the treatment of:

- Rheumatoid arthritis
- Rheumatoid (ankylosing) spondylitis
- Degenerative joint disease (osteoarthritis) of the hip
- Gout

In these conditions INDOCIN may often replace other commonly used agents such as corticosteroids, salicylates, phenylbutazone-like compounds, and colchicine.

Rheumatoid Arthritis

In many patients with chronic rheumatoid arthritis INDOCIN produces a significant decrease of pain and stiffness within 48 hours, while in other patients treatment must be continued longer before significant subjective relief or objective evidence of decreased joint swelling and tenderness occurs. Treatment with INDOCIN should be continued for at least a month before concluding that it has not produced significant benefit.

When a response to INDOCIN has been obtained, the daily salicylate requirements can usually be reduced and often stopped. Also, if patients have been receiving corticosteroids, the steroid dosage often can be gradually reduced by 25 to 50 per cent, and in some patients it can eventually be completely discontinued. In such instances the steroid dosage should be reduced slowly.

In acute rheumatoid arthritis, or in acute flares of chronic rheumatoid arthritis, INDOCIN will usually produce prompt improvement with relief of pain, tenderness, swelling and stiffness.

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Rheumatoid (Ankylosing) Spondylitis

INDOCIN frequently produces marked relief of pain and improved motion of the spine within 3 to 10 days.

Degenerative Joint Disease (Osteoarthritis) of the Hip

INDOCIN has provided relief of pain and increased range of motion in patients with degenerative joint disease of the hip.

Gout

In acute attacks of gout the response to INDOCIN is usually rapid and often dramatic. Marked reduction of pain may be obtained within 2 to 4 hours. Tenderness and heat subside within 24 to 36 hours, and swelling decreases over a 3 to 5 day period.

During the interval phase of gouty arthritis, indomethacin together with adequate doses of a uricosuric agent may provide relief of pain and prevent the recurrence of acute attacks.

CONTRAINDICATIONS

As with other anti-inflammatory agents, INDOCIN may mask the signs and symptoms of peptic ulcer. INDOCIN itself may cause peptic ulceration or irritation of the gastrointestinal tract. For these reasons it should not be given to patients with active peptic ulcer, gastritis, or ulcerative colitis, and should be used with caution if there is a history of these disorders. In 4 patients with regional enteritis treated for up to one month, and one patient treated for 6 months, INDOCIN was well tolerated. However, in view of the paucity of data, this drug should not be given to patients with regional enteritis until additional evidence of gastrointestinal tolerance is available.

Reproduction studies in mice, rats, and rabbits showed no effect on fetal development or the reproductive cycle, although in rats there was some decrease in fetal viability. Studies in mice demonstrated that INDOCIN crosses the placental barrier. Since the effects of INDOCIN on the human fetus cannot be predicted with certainty from animal studies, the safety for use in pregnant patients has not been established.

Since the experience with INDOCIN in children is limited, it is recommended that this drug should not be administered to pediatric age groups until the indications for use and dosage have been established.