placebo, diacerein 50 mg (25 mg twice daily), 100 mg (50 mg twice daily) or 150 mg (75 mg twice daily).

Treatment duration was 4 months. The primary efficacy criterion was the patient's assessment of pain on movement (for the 48 hours prior to the visit) using a 100 mm VAS. The secondary criteria included the Western Ontario and McMaster Universities Arthritis (WOMAC) Index , handicap Visual Analogue Scale (VAS), acetaminophen consumption (the only analgesic treatment authorised during the study) and the patient's and investigator's overall assessments. Clinical safety was evaluated at each visit and a full laboratory safety test was conducted 3 times during the study.

The main adverse event observed in the study was generally mild-to-moderate diarrhoea. Withdrawals due to diarrhoea were reported for 12 patients in the 150 mg/day diacerein group compared with 3 patients in each of the other 3 groups. No serious or severe adverse events regarding the upper gastrointestinal tract occurred during the study. A larger number of patients assessed safety across visits as "good" and "very good" in the 50 and 100 mg/day diacerein groups than those in the 150 mg/day diacerein group. Similar results were observed for the investigators' assessment.

Consequently, this study confirmed that the optimum dose of diacerein is 100 mg per day (50 mg twice daily).

Safety Overview

Gastrointestinal adverse events

Orally administered anthraquinone derivatives are identified to typically produce laxation within 6 – 12 hours of administration but the effect may not occur for 24 hours.