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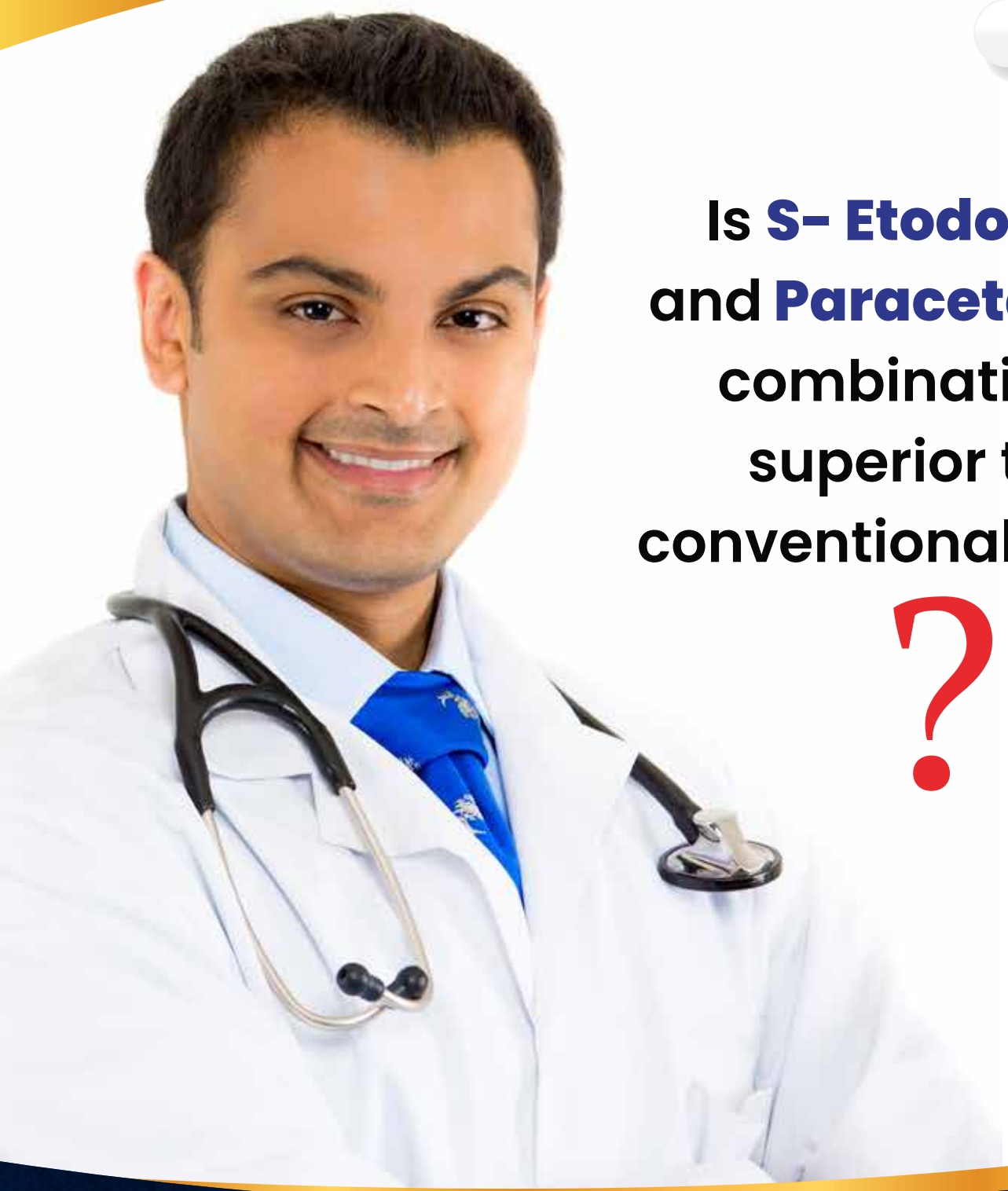

# Is S- Etodolac and Paracetamol combination superior to conventional ones ?

## Data on Indian Patients*

Multicentric, Randomized, Parallel Group Studies in Indian Patients

* Data on file

*Keep on Walking...*

# Efficacy and toleraility of two chirally pure NSAIDs in Combination with paracetamol: results of two multi-centric, randomized, parallel-group studies in Indian patients

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## Study Objective

To evaluate efficacy and tolerability of FDC* of S(+)-Etodolac and paracetamol tablet and FDC of diclofenac & paracetamol in acute musculoskeletal pain

## Study Design

Multi-centric, randomized, comparative clinical trial, 10 centers

## Study Population

111 patients with acute musculoskeletal pain enrolled

## Investigational Drugs

**Test:** FDC of S-Etodolac and paracetamol tablet twice daily

**Reference:** FDC of diclofenac and paracetamol tablet thrice daily.

* Data on file 1. Journal of Therapeutic advances/Apr-Jun,2011:Issue 1: 10-15 * FDC: Fixed Dose Combination

## Efficacy parameters for S-etodolac-paracetamol study

| Variable | S-etodolac-paracetamol study | |
|---|---|---|
| | FDC S-etodolac +paracetamol | FDC diclofenac +paracetamol |
| Responder rate n/N (%) | 49/57 (85.96) | 41/54 (75.92)[NS] |

**86%** Patient reported pain relief **Vs.** **76%** Diclofenac + Paracetamol[1]

## Adverse event occurrence in S-etodolac-paracetamol study

| Variable | S-etodolac-paracetamol study | |
|---|---|---|
| | FDC S-etodolac +paracetamol | FDC diclofenac +paracetamol |
| Hyperacidity, n/N (%) | -- | 2/54 (3.70) |
| Nausea/ Vomiting, n/N (%) | 1/57 (1.75) | 3/54 (5.55) |
| Gastritis, n/N (%) | 4/57 (7.01) | 11/54 (20.37) |
| Abdominal Discomfort, n/N (%) | 1/57 (1.75) | 3/54 (5.55%) |
| Heartburn, n/N (%) | -- | 2/54 (3.70%) |
| Total no. of patients with adverse events, n/N (%) | 5/57 (8.77) | 15/54 (26.31)[#] |

# P < 0.05

**3** times lesser adverse events than (Diclo.+ Para.)[3]

## Conclusion

The FDC of S-Etodolac and paracetamol has comparable efficacy and superior tolerability profile as compared to FDC of diclofenac and paracetamol

In **Acute Pain** associated with OA* & RA**

℞

# Proxym®-XT

S(+) Etodolac 200 mg + Paracetamol 325 mg Tablets

## The Joint Pain specialist with XTra Power




## Manufactured through Chiral Technology

## XTreme Trust

**Patients continued with Proxym-XT because it is effective**

Start with Proxym®-XT | Continue with Proxym® ER

**ABRIDGED PRESCRIBING INFORMATION: S (+) ETODOLAC AND PARACETAMOL TABLETS**

**COMPOSITION:** Each uncoated tablet contains; S (+) Etodolac 200 mg plus Paracetamol IP 325mg. **INDICATION:** For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. **DOSAGE:** Adults: The usual dose is one tablet two times daily, orally. Children: Not recommended. **CONTRAINDICATIONS:** This product should not be used in patients who have previously shown hypersensitivity to Etodolac or Paracetamol. S (+) Etodolac should not be used in patients with active peptic ulceration or a history of peptic ulcer disease (including gastrointestinal hemorrhage due to another non-steroidal anti-inflammatory drug). Due to possible cross-reactivity, S (+) Etodolac should not be administered to patients who experience asthma, rhinitis or urticaria during therapy with aspirin or other non-steroidal anti-inflammatory drugs. **PREGNANCY:** Drugs which inhibit prostaglandin biosynthesis may cause dystocia and delayed parturition as evidenced by studies in pregnant animals. Some inhibitors of prostaglandin biosynthesis have been shown to interfere with the closure of the ductus arteriosus. Safety in human pregnancy has not been established and S (+) Etodolac should not be used during pregnancy. **LACTATION:** Safety of S (+) Etodolac use during lactation has not been established and as such its use in nursing mothers should be avoided. **ADVERSE EFFECTS:** Reported side effects with Etodolac include nausea, epigastric pain, diarrhea, indigestion, heartburn, flatulence, abdominal pain, constipation, vomiting, ulcerative stomatitis, dyspepsia, gastritis, haematemesis, melaena, rectal bleeding, colitis, vasculitis, headaches, dizziness, abnormal vision, pyrexia, drowsiness, tinnitus, rash, pruritus, fatigue, depression, insomnia, confusion, paraesthesia, tremor, weakness/malaise, dyspnoea, edema, palpitations, bilirubinuria, hepatic function abnormalities and jaundice, urinary frequency, dysuria, angioedema, anaphylactoid reaction, photosensitivity, urticaria and Stevens-Johnson syndrome. More serious adverse reactions which may occasionally occur are gastrointestinal ulceration and peptic ulceration. NSAIDs have been reported to cause nephrotoxicity in various forms and their use can lead to interstitial nephritis, nephrotic syndrome and renal failure. There have been reports of nephritis and renal failure with Etodolac. Occasionally blood disorders have been reported including: thrombocytopenia, neutropenia, agranulocytosis and anemia. Following serious adverse events have been associated with Paracetamol: gastrointestinal hemorrhage, hepatotoxicity, liver failure, nephrotoxicity, pneumonitis, Stevens-Johnson syndrome and toxic epidermal necrolysis. Acute toxicity after single dose overdoses of paracetamol can be anticipated when the overdose exceeds 150 mg/kg. Chronic alcohol abusers, cachectic individuals, and persons taking pharmacologic inducers of the hepatic P450 microsomal enzyme system may be at risk with lower exposures (e.g. 5 g). **OVERDOSE:** The standard practices of gastric lavage, activated charcoal administration and general supportive therapy should be undertaken. Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol; however, the maximum protective effect is obtained up to 8 hours post-ingestion. **STORAGE:** Store in cool and dry place. **PRESENTATION:** Blister strips of 10 tablets. For further information, please consult the full prescribing information. Updated on 19.02.20

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For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only. PXT/022020/04

1. Data on file * OA: Osteoarthritis **RA: Rheumatoid Arthritis

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