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Study of Real-World Effectiveness and Tolerability in Indian Patients Receiving Etoricoxib Fast-Disintegrating Tablets for Acute Pain (SWIFT): A Prospective Multicentre Observational Evaluation

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Abstract

Background: Acute pain remains a major cause of healthcare utilization and is frequently undertreated in routine clinical practice. Etoricoxib, a selective cyclooxygenase-2 inhibitor, has established efficacy in acute pain management. Fast-disintegrating formulations may potentially facilitate earlier drug availability and improve patient acceptability. This study evaluated the real-world effectiveness, safety, and treatment acceptability of etoricoxib fast-disintegrating tablets in Indian patients with acute pain.

Methods: This prospective, multicentre, observational post-marketing surveillance study was conducted across 800 outpatient centres across India between September 2025 and February 2026. Adult patients (≥18 years) presenting with acute pain and prescribed etoricoxib fast-disintegrating tablets (120 mg once daily for up to 5 days) as part of routine clinical care were consecutively enrolled. The primary endpoint was change in pain intensity from baseline to Day 5, assessed using the Numeric Pain Rating Scale (NPRS). Secondary endpoints included time to first perceived pain relief, rescue medication use, treatment adherence, physician-reported treatment satisfaction, investigator global assessment of effectiveness and tolerability, and incidence of adverse drug reactions (ADRs).

Results: A total of 7,644 patients were enrolled and analyzed. Mean pre-dose NPRS score on Day 1 was 8.42 ± 1.67, which decreased to 5.39 ± 2.12 at 30 minutes and 3.82 ± 2.46 at 60 minutes post-dose on Day 1, corresponding to a mean reduction of 3.03 points and 4.60 points, respectively ($p < 0.001$). Pre-dose baseline NPRS progressively declined from 8.42 ± 1.67 on Day 1 to 3.52 ± 3.28 on Day 5, while Day 5 post-dose NPRS at 60 minutes decreased to 0.86 ± 1.64, indicating sustained pain control. Mean time to first perceived pain relief on Day 1 was 24 minutes 52 seconds ± 15 minutes 15 seconds. Rescue medication was required in only 417 patients (5.46%). Treatment adherence was high, with 7,593 patients (99.33%) classified as adherent. Treatment satisfaction was favorable, with 77.06% of patients rated as very satisfied and 21.82% rated as satisfied. ADRs were reported in 116 patients (1.52%), most commonly gastritis (0.26%), headache (0.17%), and dry mouth (0.14%). Most ADRs were mild or moderate in severity. No serious adverse drug reactions, deaths, or treatment discontinuations were reported.

Conclusion: In this large prospective multicentre real-world study, fast-disintegrating etoricoxib was associated with sustained reductions in pain intensity, rapid onset of pain relief, low rescue medication use, high short-term treatment adherence, and a favorable tolerability profile in Indian patients with acute pain. These findings support the real-world utility of this formulation as a treatment option in appropriately selected patients. However, randomized comparative studies against conventional etoricoxib formulations and other NSAIDs are required.

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Keywords: Acute pain; Etoricoxib; Fast-disintegrating tablet; Real-world evidence; Post-marketing surveillance; Numeric Pain Rating Scale; COX-2 inhibitor; Pain management; Treatment adherence; Safety; SWIFT.

Introduction

Acute pain remains one of the most common reasons for healthcare utilization worldwide, with pain-related complaints accounting for approximately 80% of emergency department presentations [1]. In India, pain represents a substantial healthcare burden, with nearly one-third of patients attending primary healthcare facilities presenting with pain-related complaints [2]. National treatment guidelines in India recognize pain as a major healthcare challenge and emphasize the importance of systematic pain assessment and evidence-based analgesic management [3]. Current acute pain management is guided by a multimodal analgesic approach, which combines agents with different mechanisms of action rather than relying on a single drug. Commonly used combinations include paracetamol (acetaminophen), NSAIDs such as diclofenac, ibuprofen, or ketorolac, selective COX-2 inhibitors such as celecoxib, and opioids when pain is moderate-to-severe or when non-opioid therapies are insufficient. This approach targets multiple pain pathways, improves analgesic efficacy, allows lower doses of individual drugs, and reduces dose-related toxicity and overall opioid exposure [4].

Despite this multifaceted management, acute pain remains one of the most frequent causes of healthcare utilization and continues to be inadequately managed in routine practice, often referred to as oligoanalgesia. Although current guidelines recommend multimodal analgesia using paracetamol, NSAIDs, selective COX-2 inhibitors, and opioids, when necessary, barriers such as delayed onset of action, opioid-related adverse effects, gastrointestinal intolerance, and poor adherence may contribute to inadequate pain control [5]. Etoricoxib, a selective cyclooxygenase-2 inhibitor, has demonstrated established efficacy in acute pain management. A Cochrane systematic review involving 1,214 patients undergoing acute postoperative pain models reported that a single oral dose of etoricoxib 120 mg provided clinically meaningful pain relief in approximately 66% of patients versus 12% with placebo, with a median duration of analgesia of nearly 20 hours, and adverse events comparable to placebo. Additionally, clinical studies in dental and postoperative pain have shown rapid analgesic onset, reduced rescue medication use, and efficacy comparable or superior to several conventional analgesics [5].

Etoricoxib, like many Biopharmaceutics Classification System (BCS) Class II drugs, may have its clinical performance influenced by limited aqueous solubility and dissolution-dependent absorption. This creates a formulation opportunity, particularly in acute pain settings where rapid onset of analgesia is clinically desirable [6]. Fast-disintegrating drug delivery systems have been developed to overcome such limitations by enabling rapid tablet disintegration, thereby increasing surface area available for dissolution, and potentially improving the rate of drug release and gastrointestinal availability. Formulation studies with etoricoxib fast-dissolving tablets have demonstrated significantly shorter disintegration times, enhanced dissolution profiles, and faster drug release compared with conventional tablets. These characteristics may be particularly advantageous in acute pain management, where earlier drug availability can translate into faster onset of analgesia, improved patient convenience, and better treatment adherence. A fast-disintegrating formulation of etoricoxib therefore represents a pharmacotechnical approach that may potentially offer an earlier onset of drug delivery and improved patient convenience, supporting its evaluation in real-world acute pain management [7]. While the efficacy of conventional oral etoricoxib has been well established in randomized acute pain trials, real-world data on fast-disintegrating etoricoxib across diverse acute pain etiologies remain limited. In particular, evidence regarding early onset of pain relief, treatment adherence, patient satisfaction, rescue medication use, and short-term safety in routine clinical practice is scarce. Therefore, the present multicentric prospective post-marketing surveillance study was conducted to evaluate the real-world effectiveness, safety, onset of analgesia, treatment adherence, and patient satisfaction associated with fast-disintegrating etoricoxib in Indian patients with acute pain.

Study Methods

Study Design

This was a prospective, multicentre, observational, post-marketing surveillance study conducted to evaluate the effectiveness, safety, and tolerability of etoricoxib fast-disintegrating tablets (Nucoxia XP®) in adult patients presenting with acute pain. The study was sponsored by Zydus Healthcare Limited and conducted across 800 outpatient centres across India between September 2025 and February 2026. The study was performed in accordance with the approved protocol, Good Clinical Practice (GCP) guidelines, the Declaration of Helsinki, and the New Drugs and Clinical Trial Rules, 2019.

Ethical Considerations

The study protocol, informed consent documents, and case report forms were reviewed and approved by the Central Independent Ethics Committee (CIEC), Pune, India (Approval No.: 16/2/2A/1), prior to study initiation. Written informed consent was obtained from all participants before

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enrolment.

Study Population and Patient Recruitment

Adult male or female patients aged ≥18 years presenting with acute pain in routine outpatient clinical practice were screened for eligibility. Consecutive eligible patients who were prescribed etoricoxib as part of routine physician-directed clinical care and were willing to provide informed consent were enrolled into the study. Patients were excluded if they had a known hypersensitivity to etoricoxib or other non-steroidal anti-inflammatory drugs (NSAIDs), chronic pain (>6 weeks duration), pain associated with systemic infections or malignancies, active gastrointestinal ulcer disease, severe renal impairment, cardiovascular disease (including coronary artery disease, heart failure, or unstable angina), respiratory disorders such as asthma or chronic obstructive pulmonary disease, pregnancy or lactation, participation in another clinical trial, or any other condition that, in the investigator's opinion, made participation unsuitable.

Study Treatment

Subjects received etoricoxib fast-disintegrating tablets (Nucoxia XP®) at a dose of 120 mg orally once daily for up to 5 days, as prescribed by the treating physician based on clinical judgment and pain severity. Nucoxia XP® is a fast-disintegrating formulation of etoricoxib with an approximate disintegration time of 55 seconds, developed to enable rapid analgesic onset and improved patient acceptability.

Study Drug

Nucoxia XP ® is a fast-disintegrating tablet formulation of etoricoxib, a selective cyclooxygenase-2 (COX-2) inhibitor indicated for pain management. According to internal product development data on file (Zydus Healthcare Limited), the tablet shows an *in vitro* disintegration time of approximately 55 seconds under standard testing conditions.

The formulation incorporates Opadry® EZ, a commercially available film-coating system designed to improve tablet swallowability and enhance patient experience by improving tablet mobility and reducing the likelihood of the tablet sticking in the throat or esophagus. This coating system may facilitate ease of swallowing, particularly in patients who experience difficulty swallowing conventional tablets [9]. The fast-disintegrating formulation is designed to facilitate rapid tablet disintegration and may support earlier drug availability compared with conventional solid oral dosage forms. Such formulation approaches may be particularly relevant in acute pain settings, where earlier onset of analgesia and ease of administration may improve treatment acceptability. However, the present study did not include pharmacokinetic or pharmacodynamic assessments, *in vitro* comparative dissolution testing, or direct comparison with conventional etoricoxib tablets; therefore, formulation-specific advantages in absorption, onset of action, or bioavailability cannot be directly concluded from this study.

Study Procedures

Subjects underwent two scheduled assessments:

Visit 1 (Baseline/Day 1):

Eligible subjects underwent baseline assessments including demographic data, medical history, prior medications, vital signs, and physical examination. Pain intensity was assessed using the Numeric Pain Rating Scale (NPRS). Subjects were then prescribed study treatment and provided with a subject diary for daily documentation of pain scores, dosing compliance, perceived onset of pain relief, rescue medication use, and any adverse events.

Visit 2 (Day 5 ± 1 day; End-of-Treatment/Early Termination):

Follow-up assessments were conducted either in-clinic or telephonically for subjects unable to return to the clinic. During this visit, pain intensity was reassessed, subject diaries were reviewed, treatment adherence was evaluated, rescue medication use was recorded, and adverse drug reactions (ADRs) and serious adverse drug reactions (SADRs) were documented. Investigators also performed a global tolerability assessment. Telephonic assessments were conducted using standardized assessment procedures to ensure consistency in data collection across sites.

Outcome Measures

Primary Endpoint

The primary endpoint was the change in pain intensity from baseline to Day 5/end of treatment, assessed using the Numeric Pain Rating Scale (NPRS).

Pain intensity was measured using the 11-point NPRS (0 = no pain; 10 = worst imaginable pain). Pain scores were self-reported by subjects and documented by trained investigators in the electronic case report form (eCRF). Investigators received protocol-specific training on standardized NPRS assessment before study initiation.

Secondary Endpoints

Secondary endpoints included:

- Time to first perceived pain relief following the initial dose
- Requirement for rescue analgesic medication during treatment
- Treatment adherence
- Subject satisfaction with treatment, assessed using physician-reported outcomes

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- Investigator global assessment of tolerability
- Incidence of ADRs and SADRs

Definition

Time to first pain relief was defined as the interval between administration of the first dose and the subject's first subjective perception of meaningful pain relief, as recorded in the subject diary.

Treatment adherence was assessed by reconciliation of subject diary records and investigator evaluation of dosing compliance.

Data Quality and Missing Data Handling

All study data were entered into a validated electronic data capture (EDC) system. Automated validation checks, centralized monitoring, and site query resolution procedures were used to ensure data completeness, consistency, and accuracy before database lock. Subject diary entries were reviewed by investigators and transcribed into the eCRF.

A total of 7,644 subjects were screened, enrolled, and included in the final analysis population. All enrolled patients completed end-of-treatment follow-up; however, incomplete diary entries and variable treatment durations (3–5 days) resulted in differing numbers of evaluable patients across study days. No formal imputation was performed, and analyses were based on available data at each time point. The high follow-up completion was likely facilitated by the short treatment duration and the protocol-defined option for telephonic follow-up.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows (Version 21.0; IBM Corp., Armonk, NY, USA) and R software (RStudio Version 4.2.3). Continuous variables were summarized using mean, standard deviation (SD), median, minimum, and maximum values, while categorical variables were summarized using frequencies and percentages. The primary effectiveness analysis evaluated change in NPRS scores from baseline to Day 5/end of treatment. Changes in NPRS scores were analyzed using paired sample t-tests at a two-sided significance level of 5%. Paired t-tests were considered appropriate given the within-subject repeated measurements and large sample size. Mean changes were interpreted based on both statistical significance and clinical relevance. Time to onset of pain relief was summarized using median and range. Subgroup analyses based on underlying pain etiology or diagnosis were exploratory in nature and analyzed using paired sample t-tests. Safety outcomes, including ADRs and SADRs, were summarized descriptively. As multiple NPRS assessments were conducted across five study days and four daily timepoints, p-values should be interpreted in the context of the exploratory nature of the analyses and the large sample size, which increases the statistical power to detect even small numerical differences. No formal adjustment for multiple comparisons was applied; however, effect sizes and clinical relevance (assessed against the minimum clinically important difference of approximately 1.3–2.0 NPRS points) were considered alongside statistical significance when interpreting findings. No formal imputation was performed. Analyses were based on available data for each time point. Given the exploratory nature of multiple secondary analyses, findings were interpreted in the context of effect size and clinical relevance in addition to statistical significance.

Results

Demographic Characteristics of Patients

A total of 7,644 subjects were screened, enrolled, and included in both the effectiveness and safety analyses. All enrolled subjects completed the study, with no withdrawals, losses to follow-up, or protocol deviations reported during the study period. The mean age of the study population was 50.08 ± 11.72 years, and the majority of subjects were male (5597; 73.22%) compared with female subjects (2047; 26.78%). The mean height, weight, and body mass index (BMI) were 164.27 ± 9.33 cm, 69.99 ± 10.13 kg, and 26.00 ± 3.70 kg/m², respectively. Baseline demographic characteristics are summarized in Table 1.

Table 1: Demographic characteristics of patients

Parameter	No. of Patients (N=7644)
Age (years)	50.08 (11.72)
Sex, N (%)	
Male	5597 (73.22)
Female	2047 (26.78)
Height (cms)	164.27 (9.33)
Weight (Kgs)	69.99 (10.13)
BMI (Kg/m²)	26.00 (3.70)
Medical history	
Hypertension	17 (0.22)
Thyroid disorders	11 (0.14)
Diabetes mellitus	9 (0.12)
Hypotension	5 (0.07)
GERD	3 (0.04)
Others	12 (0.15)

Data is given in Mean (SD), unless specified otherwise.

Other: Acne, Allergic rhinitis, Constipation, Fungal infection, Hyperuricemia, Insomnia, Iron deficiency, Vitamin B12 deficiency, and Vitamin D deficiency.

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Among the underlying etiologies of acute pain, back pain was the most common presentation (2336; 30.56%), followed by osteoarthritis (1675; 21.91%) and fracture-related pain (1465; 19.17%). Together, these accounted for the majority of acute pain presentations in the study population. The distribution of pain etiologies is shown in Figure 1.

Change in NPRS Scores from Baseline to 60 Minutes Post-Dose

The primary effectiveness endpoint was associated with a significant reduction in pain intensity over the treatment period, as assessed using the Numeric Pain Rating Scale (NPRS). Pre-dose baseline NPRS scores showed a progressive decline across the 5-day treatment period, decreasing from 8.42 ± 1.67 on Day 1 to 3.52 ± 3.28 on Day 5, which may suggest sustained improvement in baseline pain intensity with continued treatment. Similarly, post-dose NPRS scores assessed at 60 minutes showed consistent improvement across treatment days, decreasing from 3.82 ± 2.46 on Day 1 to 0.86 ± 1.64 on Day 5, indicating that post-dose analgesic response was maintained throughout the treatment period. On Day 1, an early reduction in pain intensity was observed as early as the time of first perceived pain relief (6.64 ± 2.03), with further reductions at 30 minutes (5.39 ± 2.12) and 60 minutes (3.82 ± 2.46) following treatment. This corresponded to a mean reduction of 3.03 points at 30 minutes and 4.60 points at 60 minutes from baseline. Changes in NPRS scores from pre-dose baseline to 60 minutes post-dose at each study day were statistically significant ($p < 0.001$). Detailed NPRS assessments are presented in Table 2, and the trend in pain reduction is illustrated in Figure 2.

Time to Onset of Pain Relief

The onset of analgesic effect was consistently rapid throughout the study period. On Day 1, the mean time to first perceived pain relief was 00:24:52 ± 00:15:15 (hh:mm:ss). Similar onset times were observed on subsequent days, ranging between approximately 24–28 minutes, with minimal day-to-day variation. These findings indicate a consistently rapid onset of pain relief associated with the fast-disintegrating formulation. Time to onset of pain relief is shown in Figure 3.

Rescue Medication Use

A small proportion of subjects (417; 5.46%) required rescue analgesic medication during the treatment period, while the majority achieved adequate pain control without additional analgesic support. Among subjects requiring rescue medication, paracetamol was the most frequently used (267; 3.49%), followed by aceclofenac (110; 1.44%) and tramadol (40; 0.52%). Rescue medication use is summarized in Table 3.

Change in Vital Signs

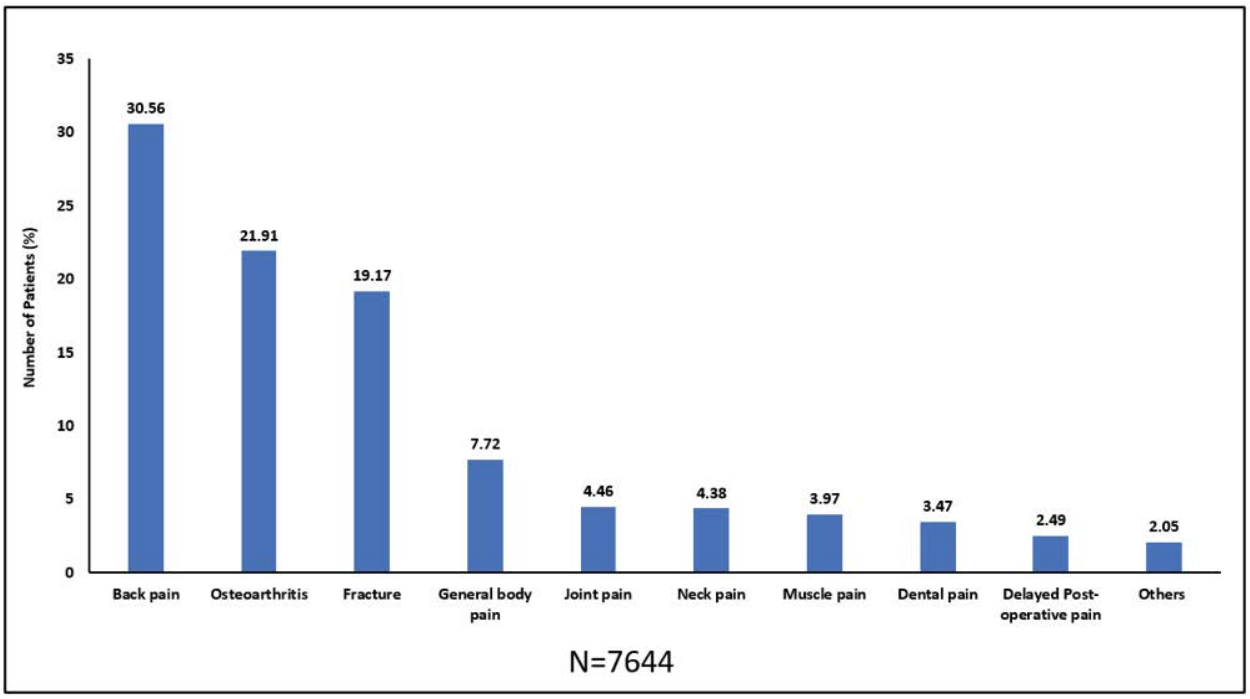

Figure 1: Etiology of Pain

Back pain was the most commonly reported etiology (30.56%), followed by osteoarthritis (21.91%) and fracture-related pain (19.17%). Other reported etiologies included general body pain, joint pain, neck pain, muscle pain, dental pain, delayed post-operative pain, and other less common acute pain conditions.

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Table 2: Change in NPRS scores from baseline to 60-minutes post-dose

Day	NPRS at Baseline	NPRS at Time of First Relief	Mean Difference (95% CI)	p-value	NPRS at 30 min	Mean Difference (95% CI)	p-value	NPRS at 60 min	Mean Difference (95% CI)	p-value
Day 1 (N=7644)	8.42 ± 1.67	6.64 ± 2.03	1.78 (1.73–1.83)	<0.001	5.39 ± 2.12	3.03 (2.98–3.08)	<0.001	3.82 ± 2.46	4.60 (4.54–4.66)	<0.001
Day 2 (N=7630)	7.07 ± 1.99	5.61 ± 2.01	1.46 (1.41–1.51)	<0.001	4.47 ± 1.91	2.60 (2.56–2.64)	<0.001	3.05 ± 2.03	4.02 (3.97–4.07)	<0.001
Day 3 (N=7595)	5.84 ± 2.40	4.64 ± 2.20	1.20 (1.15–1.25)	<0.001	3.62 ± 1.88	2.22 (2.18–2.26)	<0.001	2.30 ± 1.80	3.54 (3.50–3.58)	<0.001
Day 4 (N=7478)	4.69 ± 2.86	3.66 ± 2.48	1.03 (0.97–1.09)	<0.001	2.72 ± 2.02	1.97 (1.92–2.02)	<0.001	1.56 ± 1.69	3.13 (3.09–3.17)	<0.001
Day 5 (N=7405)	3.52 ± 3.28	2.72 ± 2.74	0.80 (0.73–0.87)	<0.001	1.91 ± 2.12	1.61 (1.56–1.66)	<0.001	0.86 ± 1.64	2.66 (2.62–2.70)	<0.001

Data are presented as mean ± SD unless otherwise specified. Mean differences are presented with 95% confidence intervals (CI). p-values were calculated using paired t-test. N represents the number of evaluable patients at each study day.

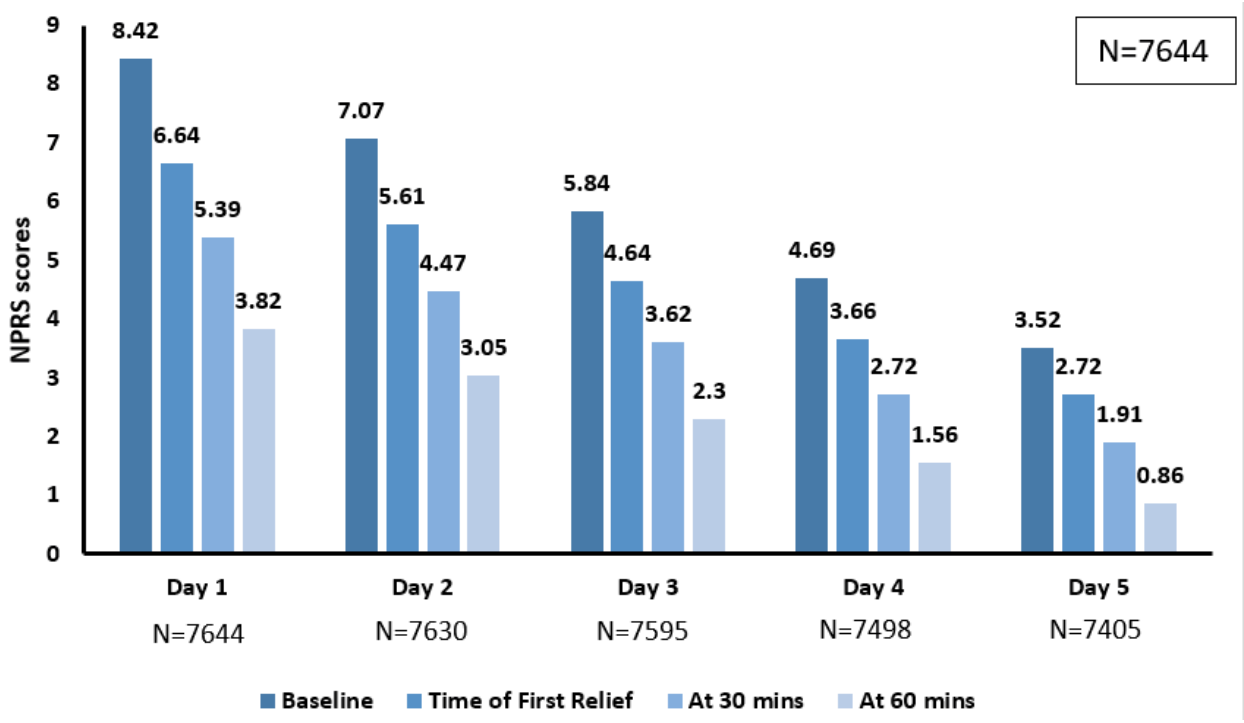

Figure 2: Reduction in mean pain intensity (NPRS)

A consistent reduction in mean NPRS scores was observed from baseline to the time of first perceived pain relief, 30 minutes, and 60 minutes post-dose across all treatment days. Mean baseline NPRS scores progressively declined from 8.42 on Day 1 to 3.52 on Day 5, while 60-minute post-dose NPRS scores decreased from 3.82 on Day 1 to 0.86 on Day 5, demonstrating both rapid onset and sustained analgesic effectiveness throughout the treatment period.

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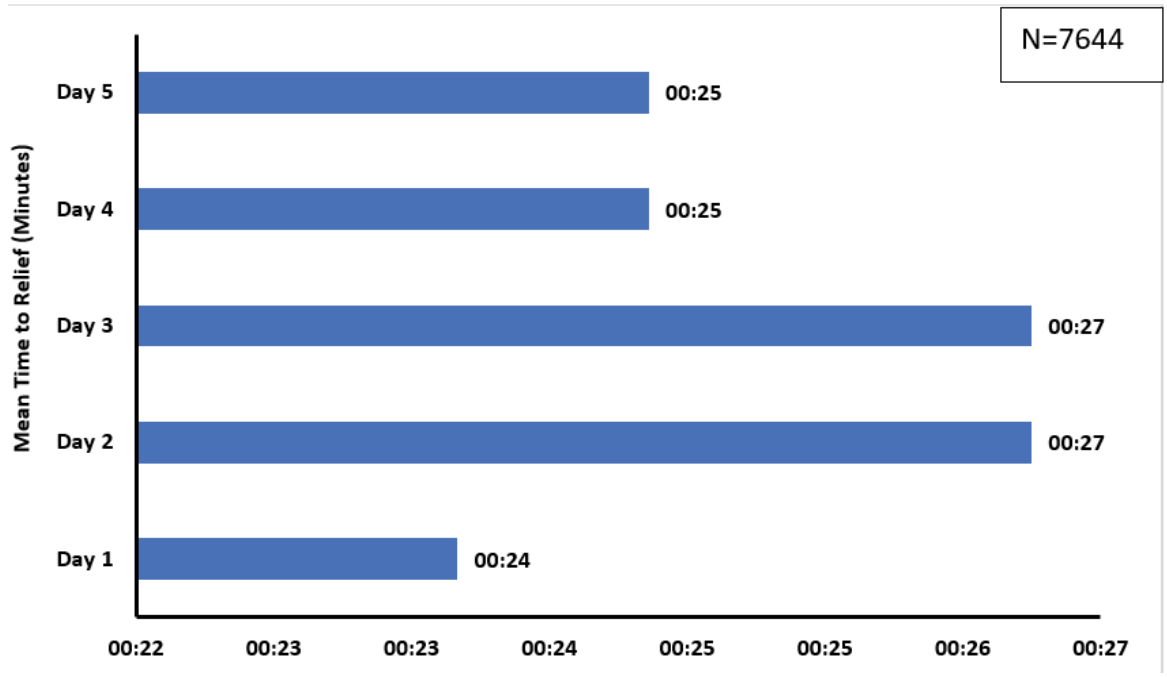

Figure 3: Time to Onset of Pain Relief

A consistently rapid onset of analgesia was observed throughout the treatment period. The mean time to first perceived pain relief was approximately 24 minutes on Day 1, 27 minutes on Days 2 and 3, and 25 minutes on Days 4 and 5, indicating sustained and reproducible early analgesic response with fast-disintegrating etoricoxib during short-term treatment.

Table 3: Overview of Rescue Medications

Medication	n	%
Any Rescue Medication	**417**	**5.46%**
Paracetamol	267	3.49%
Aceclofenac	110	1.44%
Tramadol	40	0.52%

Vital parameters remained clinically stable throughout the study period, with no clinically significant changes observed between baseline and end-of-treatment assessments. Mean systolic blood pressure changed from 128.73 ± 10.74 mmHg at baseline to 124.40 ± 7.57 mmHg at Visit 2, while diastolic blood pressure remained comparable (83.29 ± 6.51 mmHg vs. 82.33 ± 4.82 mmHg). Pulse rate, respiratory rate, and body temperature also remained within normal physiological ranges throughout the study. These findings support the favorable tolerability profile of treatment. Changes in vital signs are presented in Table 4.

Safety and Adverse Drug Reactions

Overall, Nucoxia XP demonstrated a favorable safety profile. A total of 116 subjects (1.52%) reported at least one adverse drug reaction (ADR) during the study period. The most commonly reported ADRs were gastritis (20; 0.26%), headache (13; 0.17%), and dry mouth (11; 0.14%). Most ADRs were mild (72; 0.94%) or moderate (44; 0.58%) in severity, and no severe ADRs were reported. No serious adverse drug reactions (SADRs), deaths, or treatment discontinuations due to adverse events were reported. The adverse event profile and ADR distribution are summarized in Table 5 and Table 6, respectively.

Patient Satisfaction and Physician reported outcomes

The majority of subjects rated their satisfaction with Nucoxia XP as very satisfied (5891; 77.06%) or satisfied (1667; 21.82%), with only a small proportion reporting neutral or dissatisfied outcomes. Patient satisfaction is shown

Table 4: Change in Vital Signs

Parameter	Visit 1 (N=7644)	Visit 2 (N=7644)
	(Mean ± SD)	(Mean ± SD)
Systolic Blood Pressure (mmHg)	128.73 ± 10.74	124.40 ± 7.57
Diastolic Blood Pressure (mmHg)	83.29 ± 6.51	82.33 ± 4.82
Pulse/Heart Rate (beats per minute)	78.48 ± 7.88	79.28 ± 8.54
Respiratory Rate (per minute)	17.06 ± 3.33	17.19 ± 2.08
Temperature (°C)	36.72 ± 0.80	36.44 ± 0.91

Note: N is the total number of participants enrolled into the study; n is the number of participants with respect to parameter; SD is the Standard Deviation.

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in Figure 4.

Investigator global assessment further supported these findings. Tolerability was rated as excellent in 5745 subjects (75.15%) and good in 1839 subjects (24.06%). Similarly, treatment effectiveness was rated as excellent in 5860 subjects (76.66%) and good in 1723 subjects (22.54%). Physician reported outcomes in terms of tolerability and effectiveness are presented in Figure 5.

Patient Adherence to Treatment

Table 5: Adverse Drug Reaction Profile seen in Patients

MedDRA System Organ Class (SOC)	Preferred Term	n (%)
Gastrointestinal disorders	Gastritis	20 (0.26)
	Dry mouth	11 (0.14)
	Diarrhea	10 (0.13)
	Decreased appetite	10 (0.13)
	Nausea	8 (0.10)
	Gastric discomfort	6 (0.08)
	Dyspepsia	4 (0.05)
	Flatulence	3 (0.04)
Nervous system disorders	Headache	13 (0.17)
	Dizziness	4 (0.05)
Skin and subcutaneous tissue disorders	Pruritus	8 (0.10)
	Urticaria	6 (0.08)
	Rash	5 (0.07)
General disorders and administration site conditions	Generalized weakness	4 (0.05)
Psychiatric disorders	Insomnia	4 (0.05)
Total ADR events reported		116 (1.52)

Table 6: Distribution of Adverse Drug Reaction

Parameter	Category	n (%)
Severity	Mild	72 (0.94)
	Moderate	44 (0.58)

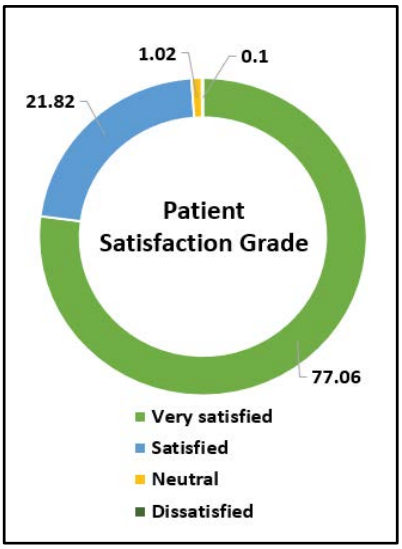

Figure 4: Patient reported Satisfaction Grading

Treatment satisfaction, assessed using physician-reported outcomes, demonstrated high overall patient satisfaction, with the majority of subjects rated as very satisfied (77.06%) or satisfied (21.82%), while only a small proportion were rated as neutral or dissatisfied.

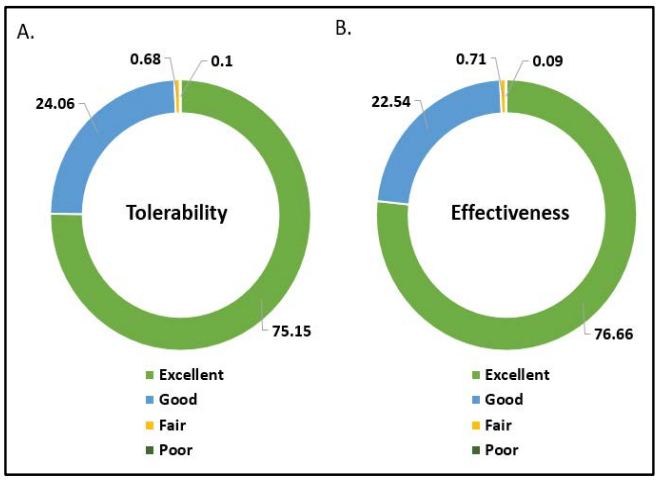

Figure 5: Physician reported outcomes A) Tolerability B) Effectiveness

(A) Tolerability: Investigators rated treatment tolerability as excellent in 75.15% of patients and good in 24.06%, while only 0.68% and 0.10% were rated as fair and poor, respectively.

(B) Effectiveness: Treatment effectiveness was rated as excellent in 76.66% of patients and good in 22.54%, with only 0.71% and 0.09% rated as fair and poor, respectively, indicating high overall physician-assessed clinical effectiveness and tolerability in routine practice.

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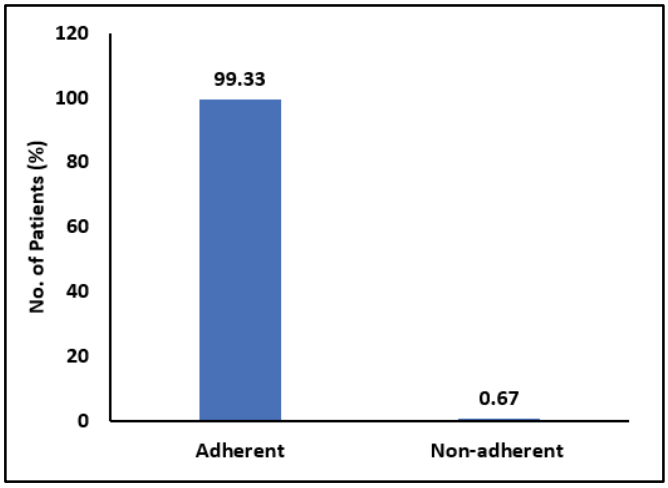

Figure 6: Patient adherence to treatment

Treatment adherence was high throughout the study, with 99.33% of patients classified as adherent to the prescribed treatment regimen, while only 0.67% were classified as non-adherent, indicating excellent short-term treatment acceptability and compliance in routine clinical practice.

Treatment adherence was excellent throughout the study period. Of the 7,644 enrolled subjects, 7593 (99.33%) were adherent to the prescribed treatment regimen, while only 51 (0.67%) were non-adherent. These findings indicate high acceptance and ease of use of Nucoxia XP in routine clinical practice. Patient adherence is shown in Figure 6.

Discussion

This large prospective multicentric post-marketing surveillance study evaluated the effectiveness and safety of fast-disintegrating etoricoxib in 7,644 Indian patients with acute pain across multiple etiologies. In the present study, mean pain intensity, measured using the Numeric Pain Rating Scale (NPRS), decreased from 8.42 ± 1.67 at pre-dose stage to 5.39 ± 2.12 at 30 minutes and 3.82 ± 2.46 at 60 minutes on Day 1, corresponding to a mean reduction of 3.03 points at 30 minutes and 4.60 points at 60 minutes. By Day 5, pre-dose pain intensity had decreased to 3.52 ± 3.28, with a further reduction to 0.86 ± 1.64 at 60 minutes post-dose, indicating sustained pain control over the treatment period. The mean NPRS reduction of 3.03 points at 30 and 4.60 at 60 minutes on Day 1 as well on all days exceeded the MCID of approximately 1.3-2 points on the NPRS, supporting the clinical meaningfulness of the observed pain reduction beyond its statistical significance. These findings are comparable with the pivotal trial by Malmstrom et al., in which etoricoxib 120 mg demonstrated significantly superior analgesic efficacy compared with ibuprofen 400 mg, with a least-squares mean pain relief using the Total Pain Relief (TOTPAR) 8 score of 22.0 versus 18.6 for ibuprofen ($P < 0.05$). The median time to onset of analgesia with etoricoxib 120 mg was 24 minutes, closely matching the onset observed in the present study. Furthermore, etoricoxib 120 mg demonstrated a duration of analgesic effect exceeding 24 hours, significantly longer than ibuprofen (10.1 hours; $P \leq 0.001$), along with lower rescue medication requirements [10]. Although the present study did not include a direct active comparator or formal TOTPAR assessment, the comparable onset of analgesia, marked early reduction in NPRS scores, progressive reduction in pre-dose intensity from 8.42 on Day 1 to 3.52 on Day 5, and low need for rescue medication suggest that the fast-disintegrating formulation provides an analgesic profile consistent with the established efficacy of conventional etoricoxib in controlled clinical trials. However, direct comparisons are limited by the differences in study design, patient populations, pain aetiologies, and outcome measures between controlled trials and real-world observational studies. Whether the fast-disintegrating formulation offers any onset advantage over conventional etoricoxib tablets cannot be determined from this study, which lacked a comparator arm. The findings from the present study are consistent with the individual patient-level meta-analysis conducted by Moore et al. evaluating oral analgesics in acute pain. In that analysis, etoricoxib 120 mg demonstrated one of the strongest responder profiles among oral analgesics, with a number needed to treat (NNT) of 1.7 for achieving at least 50% maximum pain relief over 4–6 hours. This NNT was among the best reported for commonly used oral analgesics in acute pain models, highlighting the strong analgesic efficacy of etoricoxib in controlled clinical settings [11]. The consistency between these randomized trial findings and the early pain reduction observed in the present real-world cohort further supports the clinical utility of etoricoxib in acute pain management.

High-level evidence from the Cochrane systematic review by Clarke et al., which included 1432 patients across six randomized trials, showed that a single dose of etoricoxib 120 mg (follow-up ranging from few hours to 10-14 days) is an effective analgesic, providing at least 50% pain relief to about two-thirds of treated patients with acute, moderate to severe, postoperative pain (high-quality evidence). In this systematic review by Clarke et al. it was seen that the number needed to treat to benefit (NNT) of 1.8 for at least 50% pain relief and median time to use of rescue medication of more than 20 hours are both better than other analgesics (Ibuprofen, sodium naproxen, codeine, oxycodone) commonly used for postoperative pain [5]. In a single dose it is associated with a low rate of mainly mild adverse events, similar to that with placebo. These findings support the sustained analgesic effect observed in this study, where progressive baseline pain reduction was maintained from 8.42 on Day 1 to 3.52 on Day 5. In the context of commonly used oral NSAIDs in acute pain, diclofenac 50 mg, ibuprofen 400 mg, and naproxen 550 mg are associated with NNTs of approximately 2.3, 2.5, and 2.7

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for ≥50% pain relief in postoperative pain models, somewhat less favorable than the NNT of 1.7–1.8 reported for etoricoxib 120 mg in the same setting [5, 10]. In terms of GI tolerability, selective COX-2 inhibitors such as etoricoxib and celecoxib are associated with lower rates of upper GI events compared with non-selective NSAIDs, consistent with the low GI ADR rate (gastritis 0.26%; gastric discomfort 0.08%; dyspepsia 0.05%) observed in the present study. However, the present study did not include a comparator arm, and these indirect cross-study comparisons must be interpreted with caution given differences in study design, patient populations, and pain aetiologies.

Treatment adherence in the present study was notably high, with 99.33% (7593/7644) of patients classified as adherent over the 5-day treatment period. Treatment satisfaction, assessed through physician-reported outcomes, was also high, with 77.06% of patients rated as "very satisfied" and 21.82% rated as "satisfied." While these findings may reflect favorable short-term treatment acceptability, they should be interpreted cautiously, as satisfaction was physician-assessed and adherence was based on subject diaries and investigator review over a short treatment duration. Comparable adherence-focused data for etoricoxib in acute pain are limited, particularly in real-world settings, making direct comparison difficult. The high treatment adherence and satisfaction observed in this study may be attributed to the early and sustained analgesic effect, low incidence of adverse events, and minimal requirement for rescue medication. This aligns with a study by Lin et al. which demonstrated that after switching to etoricoxib, 52% of patients achieved a clinically meaningful pain reduction (≥30%; 95% CI: 47–57%). Significant improvements were also observed in daily activity-related disability, pain interference ($P < 0.0001$), investigator global assessment ($P < 0.05$), and patient-reported treatment effectiveness, convenience, and overall satisfaction [12]. An open-label study reported that compared with prior NSAID therapy, etoricoxib was associated with improved pain control, physical functioning, and quality of life, with VAS pain scores decreasing from 59.1 mm to 27.1 mm and SF-8 physical scores improving from 33.3 to 46.3. Patient satisfaction with pain control increased from 34% to 91%. In addition, physicians reported high satisfaction with etoricoxib, with 93% satisfied with its analgesic efficacy, 95% with its anti-inflammatory profile, and 82% with its tolerability compared with prior NSAID therapy [13].

The safety findings in the present study are consistent with the established short-term safety profile of etoricoxib. Adverse drug reactions were reported in 1.52% (116/7644) of patients, with gastritis (0.26%), headache (0.17%), and dry mouth (0.14%) being the most frequently reported events. No serious adverse drug reactions, deaths, or treatment discontinuations occurred. These findings are consistent with NICE study where 98.69% of patients did not report any adverse events [14]. Another Multinational Etoricoxib and Diclofenac Arthritis Long-term (MEDAL) programme showed that rates of upper gastrointestinal clinical events (perforation, bleeding, obstruction, ulcer) were lower with etoricoxib than with diclofenac (0·67 vs 0·97 per 100 patient-years; hazard ratio 0·69 [0·57–0·83]) [15]. The low incidence of adverse drug reactions in present study should be interpreted in the context of the short treatment duration and exclusion of patients with major cardiovascular disease, severe renal impairment, active gastrointestinal ulcer disease, asthma/COPD, pregnancy, and lactation. Therefore, these findings may not be directly generalizable to higher-risk patient populations.

The early onset of analgesia observed in the present study, with mean time to first pain relief of approximately 24.8 minutes, may be partly supported by emerging formulation evidence for fast-dissolving etoricoxib systems. In a recent study, Elsegaie et al. demonstrated that solid dispersion-based fast-dissolving etoricoxib tablets significantly improved dissolution behavior and predicted oral bioavailability [16]. Similarly, Mahapatra et al. reported enhanced solubility and dissolution kinetics with etoricoxib oro-dispersible tablets designed for faster onset of action [17]. In another formulation study, Sharma et al. reported 88% drug release within 15 minutes and a disintegration time of 21 seconds with an immediate-release etoricoxib system [7]. Although these formulation studies did not evaluate clinical pain outcomes, they provide mechanistic plausibility for the rapid analgesic onset observed in the present real-world study.

Overall, the present findings support the real-world utility of fast-disintegrating etoricoxib as a treatment option in appropriately selected patients with acute pain. However, randomized head-to-head comparative studies against conventional etoricoxib tablets and other oral NSAIDs are needed to determine whether the fast-disintegrating formulation offers clinically meaningful advantages in onset of action, adherence, tolerability, or overall patient experience.

Limitations

This study has several limitations. The single-arm observational design without randomization or an active comparator arm limits causal inference and prevents direct comparison with conventional etoricoxib tablets or other analgesic strategies. The post-marketing, company-sponsored nature of the study may introduce potential selection and reporting bias. The inclusion of heterogeneous acute pain etiologies may have influenced treatment response across clinical subgroups. Pain intensity, time to onset of relief, and treatment satisfaction were partly based on subject diaries and

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physician-reported assessments, which may introduce recall or reporting bias. Use of rescue medication in a subset of patients may have partially confounded pain outcomes. The short follow-up duration (5 days) limits conclusions regarding long-term safety, sustained adherence, or recurrence of pain.

The absence of pharmacokinetic/pharmacodynamic (PK/PD) assessment prevents mechanistic confirmation of whether the fast-disintegrating formulation offers formulation-specific advantages over conventional etoricoxib tablets. In addition, exclusion of patients with major cardiovascular disease, severe renal impairment, active gastrointestinal ulcer disease, respiratory disease, pregnancy, and lactation limits the generalizability of safety findings to higher-risk populations.

Future scope

Future randomized controlled head-to-head studies comparing fast-disintegrating etoricoxib with conventional etoricoxib tablets and other commonly used NSAIDs are warranted to determine whether formulation-related differences translate into clinically meaningful improvements in onset of analgesia, treatment adherence, patient satisfaction, and long-term safety. Studies incorporating pharmacokinetic/pharmacodynamic assessments, indication-specific acute pain populations, and longer follow-up durations would further strengthen the clinical positioning of this formulation.

Conclusion

In this large prospective multicentric real-world study, fast-disintegrating etoricoxib was associated with early and sustained reductions in pain intensity in Indian patients with acute pain, with clinically meaningful improvements in NPRS scores observed within 30–60 minutes of treatment initiation and continued improvement over the 5-day treatment period. Pain relief was typically reported within approximately 25 minutes, and the low requirement for rescue medication suggests effective pain control in the majority of treated patients. High treatment satisfaction and excellent adherence further support its acceptability in routine clinical practice. In addition, the low incidence of adverse drug reactions, most of which were mild to moderate in severity, absence of serious adverse drug reactions, and stable vital parameters suggest a favorable short-term safety and tolerability profile. These findings support the real-world utility of this formulation as a treatment option in appropriately selected patients with acute pain. However, given the observational single-arm design and short follow-up duration, comparative studies against conventional etoricoxib formulations and other NSAIDs are warranted to determine whether the formulation offers clinically meaningful advantages in onset of action, adherence, tolerability, or overall patient experience.

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Conflict of Interest

Sameer Muchhala and Vidhya Natarajan are employee of Zydus Healthcare Limited (ZHL). The remaining authors declare no conflicts of interest related to this work.

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