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Dyloject (Diclofenac Sodium for Injection)

??? ??????: 30 ??????/?????? 2017

The following serious adverse reactions are discussed elsewhere in the labeling:

-]**WARNINGS AND PRECAUTIONS** and **BOXED WARNING** Cardiovascular thrombotic events [see
-]**WARNINGS AND PRECAUTIONS** and **BOXED WARNING** Gastrointestinal effects [see
-]**WARNINGS AND PRECAUTIONS** and **CONTRAINDICATIONS** Renal effects [see
-]**WARNINGS AND PRECAUTIONS** Hepatic effects [see
-]**WARNINGS AND PRECAUTIONS** Hypertension [see
-]**WARNINGS AND PRECAUTIONS** Congestive heart failure and edema [see
-]**WARNINGS AND PRECAUTIONS** Anaphylactoid reactions [see
-]**WARNINGS AND PRECAUTIONS** Serious skin reactions [see

Adverse reactions from clinical studies of Dyloject

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

During clinical development, 1,156 patients were exposed to Dyloject in multiple-dose, controlled and open-label studies. Dyloject was administered post-surgically -every 6 hours for up to 5 days. The incidence rates of adverse reactions listed in the following table are derived from multicenter, controlled clinical studies in post operative patients comparing Dyloject to placebo in patients who may have also received morphine rescue medication.

-Table 1: Proportion of Patients Experiencing Common Adverse Reactions in Placebo-Controlled Clinical Studies in Patients with Acute Moderate-to Severe Postoperative Pain occurring in greater than or equal to 3% in patients treated with Dyloject*

Dyloject N=187	Placebo N=126	MedDRA Preferred Term
146 (78%)	104 (83%)	Any Reaction
45 (24%)	50 (40%)	Nausea
25 (13%)	14 (11%)	Constipation
19 (10%)	20 (16%)	Headache
19 (10%)	10 (8%)	Infusion Site Pain
15 (8%)	2 (2%)	Dizziness
15 (8%)	20 (16%)	Flatulence
12 (6%)	23 (18%)	Vomiting
11 (6%)	12 (10%)	Insomnia
9 (5%)	10 (8%)	Pruritus
9 (5%)	6 (5%)	Hypotension
8 (4%)	13 (10%)	Pyrexia
8 (4%)	9 (7%)	Anemia
6 (3%)	1 (1%)	Infusion Site Extravasation
*Intravenous morphine was permitted as rescue medication for pain management.		

Adverse Reactions From Clinical Studies Or Spontaneous Reports For Other Formulations Of Diclofenac And Other NSAIDs

In patients taking diclofenac or other NSAIDs, the most frequently reported adverse reactions occurring in approximately 1%-10% of patients are:

Gastrointestinal experiences including abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, nausea, GI ulcers (gastric/duodenal) and vomiting.

Abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headaches, increased bleeding time, pruritus, rashes and tinnitus.

Additional adverse reactions reported occasionally include:

fever, infection, sepsis **Body as a Whole:**

congestive heart failure, hypertension, tachycardia, syncope **Cardiovascular System:**

esophagitis, gastric/peptic ulcers, gastritis, gastrointestinal bleeding, glossitis, hematemesis, hepatitis, jaundice **Digestive System:**

ecchymosis, eosinophilia, leukopenia, melena, purpura, rectal bleeding, stomatitis, thrombocytopenia **Hemic and Lymphatic System:**

weight changes **Metabolic and Nutritional:**

anxiety, asthenia, confusion, depression, dream abnormalities, drowsiness, insomnia, malaise, nervousness, paresthesia, somnolence, tremors, **Nervous System:** vertigo

asthma, dyspnea **Respiratory System:**

alopecia, photosensitivity, sweating increased **Skin and Appendages:**

blurred vision **Special Senses:**

cystitis, dysuria, hematuria, interstitial nephritis, oliguria/polyuria, proteinuria, renal failure **Urogenital System:**

Other adverse reactions, which occur rarely are:

anaphylactic reactions, appetite changes, death **Body as a Whole:**

arrhythmia, hypotension, myocardial infarction, palpitations, vasculitis **Cardiovascular System:**

colitis, eructation, fulminant hepatitis with and without jaundice, liver failure, liver necrosis, pancreatitis **Digestive System:**

agranulocytosis, hemolytic anemia, aplastic anemia, lymphadenopathy, pancytopenia **Hemic and Lymphatic System:**

hyperglycemia **Metabolic and Nutritional:**

convulsions, coma, hallucinations, meningitis **Nervous System:**

respiratory depression, pneumonia **Respiratory System:**

angioedema, toxic epidermal necrolysis, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, urticaria **Skin and Appendages:**

conjunctivitis, hearing impairment **Special Senses:**

Adverse Reactions of Special Interest

Based on the analysis of the pooled data from the multi-dose, controlled clinical trials, postoperative patients treated with Dyloject had more adverse reactions related to wound healing (7.5%) compared to patients treated with placebo (4%).