**Important Safety Information for Tolectin®DS (Tolmetin Sodium)**

**Cardiovascular Risk**

- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

- TOLECTIN is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery

**Gastrointestinal Risk**

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

**Indications and Usage**

- Carefully consider the potential benefits and risks of TOLECTIN®DS and other treatment options before deciding to use TOLECTIN®DS. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals.
- TOLECTIN®DS (tolmetin sodium) is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis. TOLECTIN®DS is indicated in the treatment of acute flares and the long-term management of the chronic disease.
- TOLECTIN®DS is also indicated for treatment of juvenile rheumatoid arthritis. The safety and effectiveness of TOLECTIN®DS have not been established in pediatric patients under 2 years of age.

**Contraindications**

- Tolmetin Sodium is contraindicated in patients with known hypersensitivity to tolmetin or any components of the formulation.
- Tolmetin Sodium should not be given to patients who have experienced asthma, urticaria or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.
- Tolmetin Sodium should not be used for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

**Warnings and Precautions:**

1. **Cardiovascular Thrombotic Events:** Tolmetin Sodium, like other NSAIDs, may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

2. **Hypertension** - NSAIDs, including TOLECTIN®DS, can lead to onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Blood pressure (BP) should be monitored closely during the initiation of NSAID treatment and throughout the course of therapy.
3. **Congestive Heart Failure -** Fluid retention and edema have been observed in some patients taking NSAIDs. TOLECTIN®DS should be used with caution in patients with fluid retention or heart failure.
4. **Gastrointestinal Bleeding, Ulceration, and Perforation:** Tolmetin Sodium can cause serious gastrointestinal adverse events, including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events may occur at any time during treatment, with or without warning symptoms. Elderly patients and those with a history of gastrointestinal ulcers or bleeding are at increased risk.
5. **Hepatotoxicity:** Tolmetin Sodium may cause elevations in liver enzymes and liver injury. Severe hepatic reactions, including jaundice and fatal fulminant hepatitis, have occurred. Patients with preexisting liver disease or those taking other hepatotoxic medications may be at increased risk.
6. **Renal Toxicity:** NSAIDs, including Tolmetin Sodium, can cause renal adverse reactions, including acute renal failure, which may be reversible upon discontinuation of the drug. Patients with preexisting renal dysfunction, heart failure, dehydration, or those taking diuretics are at increased risk.
7. **Hematologic Effects:** Tolmetin Sodium may inhibit platelet aggregation and prolong bleeding time. Patients taking anticoagulants or those with bleeding disorders may be at increased risk of bleeding complications.
8. **Anaphylactic Reactions:** Tolmetin Sodium can cause severe allergic reactions, including anaphylaxis, which may be fatal. Patients with a history of allergic reactions to NSAIDs should avoid Tolmetin Sodium.
9. **Serious Skin Reactions:** Tolmetin Sodium can cause serious skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, which may be fatal. These reactions can occur without warning. Patients should discontinue Tolmetin Sodium at the first appearance of rash or skin lesions.

**Pregnancy and Lactation:**

- Tolmetin Sodium should be avoided in the third trimester of pregnancy due to the risk of premature closure of the ductus arteriosus.
- Tolmetin Sodium is not recommended during breastfeeding, as it may be excreted in breast milk.

**Adverse Reactions:**

- The most common adverse reactions (≥1%) reported with Tolectin®DS include gastrointestinal disturbances (e.g., abdominal pain, dyspepsia, nausea, diarrhea), dizziness, headache, and rash.
- Other adverse reactions may include gastrointestinal ulceration, hepatotoxicity, renal toxicity, anemia, hypertension, and edema.

**Drug Interactions:**

- Tolmetin Sodium may interact with other medications, including but not limited to anticoagulants, antiplatelet agents, diuretics, lithium, methotrexate, SSRIs, and ACE inhibitors. Patients should inform their healthcare provider of all medications they are taking.

**Overdosage:**

- In case of overdose, seek immediate medical attention. Symptoms of overdose may include nausea, vomiting, epigastric pain, gastrointestinal bleeding, dizziness, headache, tinnitus, confusion, and in severe cases, metabolic acidosis, coma, and respiratory depression.

**Reporting Adverse Events:**

- Healthcare professionals and patients should report any adverse events associated with Tolectin to the FDA's MedWatch program at 1-800-FDA-1088 or www.fda.gov/medwatch.

**For additional information about Tolectin®DS, please refer to the full prescribing information.**