

## DR. REDDY'S LABORATORIES LTD.

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## Dr. Reddy's Laboratories and Senores Pharmaceuticals, Inc. announce the launch Ketorolac Tromethamine Tablets USP, 10 mg in the U.S. market

Hyderabad, India, May 24, 2022

For immediate release

Hyderabad, India and Princeton, NJ, USA. May 24, 2022 — Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's") and Senores Pharmaceuticals, Inc. today announced the launch of Ketorolac Tromethamine Tablets USP, 10 mg, a therapeutic generic equivalent of the reference listed drug Toradol Tablets, 10 mg in the U.S. market approved by the U.S. Food and Drug Administration (USFDA).

Ketorolac Tromethamine Tablets USP, 10 mg, is a nonsteroidal anti-inflammatory drug ("NSAID") indicated for the short-term (up to 5 days in adults) management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation treatment following intravenous or intramuscular dosing of ketorolac tromethamine, if necessary.

"We are pleased to partner with Dr. Reddy's Laboratories for the commercial launch of Ketorolac Tromethamine Tablets in the U.S. market," states Dhananjay Barot, Director, Senores Pharmaceuticals, Inc.

"Our constant dedication has contributed to expanding our product portfolio, and today we are a significant and reliable supplier of this product," states Swapnil Shah, Managing Director, Senores Group.

"We are excited about this launch, and pleased to partner with Senores to create affordable access to this product and expand our portfolio in the US market," says Marc Kikuchi, CEO, North America Generics, Dr. Reddy's Laboratories.

The Toradol Tablets, 10 mg brand and generic had U.S. sales of approximately \$16.8 million MAT for the most recent twelve months ending in March 2022 according to IQVIA\*.

Dr. Reddy's Ketorolac Tromethamine Tablets USP, 10 mg, are available in bottle count sizes of 100.

Please [click here](#) to see the full prescribing information and approved indication, along with boxed warning for Dr. Reddy's Ketorolac Tromethamine Tablets USP, 10 mg.

### BOXED WARNING

**Ketorolac tromethamine tablets, a nonsteroidal anti-inflammatory drug (NSAID), are indicated for the short-term (up to 5 days in adults), management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation treatment following IV or IM dosing of ketorolac tromethamine, if necessary. The total combined duration of use of ketorolac tromethamine tablets and ketorolac tromethamine should not exceed 5 days.**

**Ketorolac tromethamine tablets are not indicated for use in pediatric patients and they are NOT indicated for minor or chronic painful conditions. Increasing the dose of ketorolac tromethamine tablets beyond a daily maximum of 40 mg in adults will not provide better efficacy but will increase the risk of developing serious adverse events.**

### GASTROINTESTINAL RISK

- Ketorolac tromethamine, including ketorolac tromethamine tablets can cause peptic ulcers, gastrointestinal bleeding and/or perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Therefore, ketorolac tromethamine is CONTRAINDICATED in patients with active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation, and in patients with a history of peptic ulcer disease or gastrointestinal bleeding. Elderly patients are at greater risk for serious gastrointestinal events (see **WARNINGS**).

## CARDIOVASCULAR THOMBOTIC EVENTS

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use (see **WARNINGS** and **PRECAUTIONS**).
- Ketorolac tromethamine tablets are contraindicated in the setting of coronary artery bypass graft (CABG) surgery (see **CONTRAINDICATIONS** and **WARNINGS**).

## RENAL RISK

- Ketorolac tromethamine is CONTRAINDICATED in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion (see **WARNINGS**).

## RISK OF BLEEDING

- Ketorolac tromethamine inhibits platelet function and is, therefore, CONTRAINDICATED in patients with suspected or confirmed cerebrovascular bleeding, patients with hemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding (see **WARNINGS** and **PRECAUTIONS**).

**Ketorolac tromethamine is CONTRAINDICATED as prophylactic analgesic before any major surgery.**

## RISK DURING LABOR AND DELIVERY

- The use of ketorolac tromethamine in labor and delivery is contraindicated because it may adversely affect fetal circulation and inhibit uterine contractions.

## CONCOMITANT USE WITH NSAIDs

- Ketorolac tromethamine is CONTRAINDICATED in patients currently receiving aspirin or NSAIDs because of the cumulative risk of inducing serious NSAID-related side effects.

## SPECIAL POPULATIONS

- Dosage should be adjusted for patients 65 years or older, for patients under 50 kg (110 lbs) of body weight (see **DOSAGE AND ADMINISTRATION**) and for patients with moderately elevated serum creatinine (see **WARNINGS**).

## Important Safety Information: Ketorolac Tromethamine Tablets, 10 mg

### What Important Information Should I Know About Ketorolac Tromethamine Tablets, 10 mg?

- **GASTROINTESTINAL RISK:** Ketorolac tromethamine, including ketorolac tromethamine tablets can cause peptic ulcers, gastrointestinal bleeding and/or perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Therefore, ketorolac tromethamine is CONTRAINDICATED in patients with active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation, and in patients with a history of peptic ulcer disease or gastrointestinal bleeding. Elderly patients are at greater risk for serious gastrointestinal events.
- **CARDIOVASCULAR THOMBOTIC EVENTS:** Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. Ketorolac tromethamine tablets are contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
- **RENAL RISK:** Ketorolac tromethamine is CONTRAINDICATED in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion.
- **RISK OF BLEEDING:** Ketorolac tromethamine inhibits platelet function and is, therefore, CONTRAINDICATED in patients with suspected or confirmed cerebrovascular bleeding, patients with hemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding. **Ketorolac tromethamine is CONTRAINDICATED as prophylactic analgesic before any major surgery.**
- **RISK DURING LABOR AND DELIVERY:** The use of ketorolac tromethamine in labor and delivery is contraindicated because it may adversely affect fetal circulation and inhibit uterine contractions.
- **CONCOMITANT USE WITH NSAIDs:** Ketorolac tromethamine is CONTRAINDICATED in patients currently receiving aspirin or NSAIDs because of the cumulative risk of inducing serious NSAID-related side effects.

- **SPECIAL POPULATIONS:** Dosage should be adjusted for patients 65 years or older, for patients under 50 kg (110 lbs) of body weight.

### Who Should Not Use Ketorolac Tromethamine Tablets, 10 mg?

- Ketorolac tromethamine is contraindicated in patients with previously demonstrated hypersensitivity to ketorolac tromethamine
- Ketorolac tromethamine is contraindicated in patients with active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation
- Ketorolac tromethamine 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.
- right before or after heart bypass surgery
- The concomitant use of ketorolac tromethamine and probenecid is contraindicated
- The concomitant use of ketorolac tromethamine and pentoxifylline is contraindicated

### What Should I Tell My Healthcare Ketorolac Tromethamine Tablets, 10 mg?

Before taking Ketorolac Tromethamine Tablets, tell your doctor if you:

- have liver or kidney problems
- have high blood pressure
- have asthma
- are pregnant or plan to become pregnant. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs after about 30 weeks of pregnancy.
- are breastfeeding or plan to breast feed.

### What Are the Possible Side Effects of Ketorolac Tromethamine Tablets, 10 mg?

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| • new or worse high blood pressure       | • heart failure   |
| • liver problems including liver failure | • kidney problems including kidney failure                        |
| • life-threatening skin reactions        | • low red blood cells (anemia)                                    |
| • life-threatening allergic reactions    | • shortness of breath or trouble breathing                        |
| • slurred speech                         | • chest pain  |
| • swelling of the face or throat         | • weakness in one part or side of your body                       |
| • nausea                                 | • vomit blood   |
| • more tired or weaker than usual        | • blood in your bowel movement or it is black and sticky like tar |
| • diarrhea                               | • unusual weight gain   |
| • itching                                | • skin rash or blisters with fever                                |
| • your skin or eyes look yellow          | • swelling of the arms, legs, hands and feet                      |
| • indigestion or stomach pain            | • flu-like symptoms   |

These are not all of the possible side effects of Ketorolac Tromethamine Tablets, 10 mg. Call your doctor for medical advice about side effects. For more information, ask your doctor or pharmacist. You are encouraged to report negative side effects of prescription drugs. To report suspected side effects, call Dr. Reddy's Laboratories Medical Information Call Center at 1-888-DRL-DRUG (1-888-375-3784) or via email to [medinfo@drreddys.com](mailto:medinfo@drreddys.com) or contact the US FDA at 1-800-FDA-1088 (1-800-332-1088) or online at <http://www.fda.gov/safety/medwatch>. Please refer to the Ketorolac Tromethamine Tablets, 10 mg Package Inserts for full Prescribing Information and Instructions for Use

### Indication and Usage for Ketorolac Tromethamine Tablets, 10 mg

- Ketorolac tromethamine tablets, a nonsteroidal anti-inflammatory drug (NSAID), are indicated for the short-term (up to 5 days in adults), management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation treatment following IV or IM dosing of ketorolac tromethamine, if necessary. The total combined duration of use of ketorolac tromethamine tablets and ketorolac tromethamine should not exceed 5 days.

\*IQVIA Retail and Non-Retail MAT March 2022.

RDY-0522-410

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**About Dr. Reddy's:** Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: [www.drreddys.com](http://www.drreddys.com)

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**About Senores Pharmaceuticals, Inc.**

Senores Pharmaceuticals, based in Atlanta, Georgia is one of the fastest-growing pharmaceutical companies in the U.S. market. Currently, the company has more than 15 products commercially launched or filed with the USFDA. For more information, visit [www.senorespharma.com](http://www.senorespharma.com)

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Disclaimer: This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets, credit defaults , currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events, (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2021. The company assumes no obligation to update any information contained herein.  
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