Press Release



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Dr. Reddy's Laboratories announces the launch of Icosapent Ethyl Capsules, 1 gram in the U.S. Market

Hyderabad, India, June 22, 2021

For Immediate Release

Hyderabad, India and Princeton, NJ, USA. June 22, 2021 — Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's") today announced the launch of Icosapent Ethyl Capsules, 1 gram approved by the U.S. Food and Drug Administration (USFDA).

Dr. Reddy's Icosapent Ethyl Capsules, 1 gram is approved for the following indication: as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Please note that Dr. Reddy's Icosapent Ethyl Capsules is not approved for the following indication: as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

<u>Limitations of Use</u>: The effect of Icosapent Ethyl Capsules on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Dr. Reddy's Icosapent Ethyl is available in 1 gram capsules in bottle count size of 120's count.

Please click here to see the full prescribing information along with the approved indication for Dr. Reddy's Icosapent Ethyl Capsules: https://www.drreddys.com/pi/icosapent-ethyl-1g-pi.pdf.

Important Safety Information: Icosapent Ethyl Capsules, 1 Gram

What Important Information Should I Know About Icosapent Ethyl Capsules, 1 Gram?

- Icosapent Ethyl is associated with an increased risk of heart arrhythmias (atrial fibrillation or atrial flutter) requiring hospitalization
- Potential allergic reactions in patients with fish and/or shellfish allergy
- Please discontinue and seek medical attention if you experience any reactions
- Icosapent Ethyl is associated with an increased risk of bleeding. The incidence of bleeding
 is greater in patients receiving concomitant antithrombotic medications, such as aspirin,
 clopidogrel, or warfarin

Who Should Not Use Icosapent Ethyl Capsules, 1 Gram?

• Icosapent Ethyl Capsules should not be used in patients with known hypersensitivity (e.g. anaphylactic reaction) to Icosapent Ethyl or any of its ingredients

What Should I Tell My Healthcare Provider Before Taking Icosapent Ethyl Capsules, 1 Gram?

Before taking Icosapent Ethyl Capsules, tell your doctor if you:

- Have diabetes
- Have been diagnosed with low thyroid levels (hypothyroidism)
- Have a known liver condition
- Have a known pancreas condition
- Have fish and/or shellfish allergies
- Are pregnant, or planning to become pregnant
- Are breastfeeding or plan to breastfeed

Provide your doctor with a complete list of medications you take, including prescription and overthe-counter medicines, vitamins, and dietary or herbal supplements. Icosapent Ethyl Capsules can interact with certain other medicines that you are taking.

Tell your doctor if you take medicines that affect your blood clotting (anticoagulants or blood thinners).

What Are the Possible Adverse Reactions of Icosapent Ethyl Capsules, 1 Gram?

Call your doctor or get emergency help right away if you develop:

- Heart arrhythmias (atrial fibrillation or atrial flutter) Heart arrhythmias which can be serious and cause hospitalization have happened in people who take Icosapent Ethyl Capsules, especially in people who have heart (cardiovascular) disease or diabetes with a risk factor for heart (cardiovascular) disease, or who have had heart arrhythmias in the past. Tell your doctor if you get any symptoms of heart arrhythmias such as feeling as if your heart is beating fast and irregular, lightheadedness, dizziness, shortness of breath, chest discomfort, or you faint
- Potential allergic reactions if you are allergic to fish and/or shellfish
- **Bleeding** Serious bleeding may occur while using Icosapent Ethyl Capsules. Increased risk of bleeding may occur if also taking blood thinners

If you have a liver condition and are taking Icosapent Ethyl Capsules, your doctor should do blood tests during treatment.

The most common adverse reactions include:

- Muscle and joint pain (musculoskeletal pain)
- Swelling of the hands, legs, or feet (peripheral edema)
- Constipation
- Gout
- Heart arrhythmias (atrial fibrillation)

Please refer to the Package Insert for full prescribing information for Icosapent Ethyl Capsules. These are not all of the possible side effects of Icosapent Ethyl Capsules. Call your doctor for medical advice about side effects. For more information, ask your healthcare provider 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 Hotline at 1-888-DRL-DRUG (1-888-375-3784) or via email to 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.

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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. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – 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.

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, 2020. The company assumes no obligation to update any information contained herein."