Dr. Reddy's Laboratories announces the launch of Phytonadione Injectable Emulsion USP, 10 mg/ml Single-Dose Ampules in the U.S. Market

Hyderabad, India, June 22, 2019

For Immediate Release

Hyderabad, India and Princeton, NJ, USA. June 22, 2019—Dr. Reddy’s Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, along with its subsidiaries together referred to as “Dr. Reddy’s”) today announced the launch of Phytonadione Injectable Emulsion USP, 10 mg/ml Single-Dose Ampules, a therapeutic equivalent generic version of Vitamin K1 (Phytonadione) Injectable Emulsion USP, 10 mg/ml, approved by the U.S. Food and Drug Administration (USFDA).

“We’re pleased to bring this product to market for the customers and patients who will benefit from access to this medicine and who have in the past experienced supply disruptions in the market place,” explains Marc Kikuchi, Chief Executive Officer, North America Generics, Dr. Reddy’s Laboratories. “This is a great addition to our injectable offering in the U.S. market as we continue to augment our portfolio to drive growth for the Global Hospitals segment.”

The Vitamin K1 (Phytonadione) for Injectable Emulsion USP, 10 mg/ml brand and generic had combined U.S. sales of approximately $46.6 million MAT for the most recent twelve months ending in April 2019 according to IQVIA Health*.

Dr. Reddy’s Phytonadione Injectable Emulsion USP, 10 mg/ml Single-Dose Ampules is available in 1 mL Ampule containing 10 mg/mL of Phytonadione.

WARNING: INTRAVENOUS AND INTRAMUSCULAR USE

Severe reactions, including fatalities, have occurred during and immediately after INTRAVENOUS injection of phytonadione, even when precautions have been taken to dilute the phytonadione and to avoid rapid infusion. Severe reactions, including fatalities, have also been reported following INTRAMUSCULAR administration. Typically these severe reactions have resembled hypersensitivity or anaphylaxis, including shock and cardiac and/or respiratory arrest. Some patients have exhibited these severe reactions on receiving phytonadione for the first time.

Therefore the INTRAVENOUS and INTRAMUSCULAR routes should be restricted to those situations where the subcutaneous route is not feasible and the serious risk involved is considered justified.

*IQVA Retail and Non-Retail MAT April 2019
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About Dr. Reddy’s: Dr. Reddy’s Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) 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
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