

Zydus receives Final Approval from the USFDA for Methylene Blue Injection

Ahmedabad, India, December 6, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as “Zydus”) has received final approval from the United States Food and Drug Administration (USFDA) to manufacture and market Methylene Blue Injection, 10mg/2ml and 50mg/5ml. Zydus’ Methylene Blue Injection, 10mg/2ml and 50mg/5ml. is the generic version of the Reference Listed Drug (RLD) ProvayBlue® Injection.

The majority of current market usage is still on the ampoule presentation whereas Zydus is offering a generic version of Methylene Blue injection in vial presentation. From a hospital perspective, vial presentation is an affordable option with significant benefit and advantage. Vial presentation has no risk of Glass particulate contamination like in ampoules and provides various benefits like ease of use, handlings and flexible option with reduced dose waste.

"Zydus is pleased to introduce Methylene Blue Injection, 10mg/2ml and 50mg/5ml in the U.S., continuing our commitment to supply affordable complex generic medications to patients in need and strengthening the U.S. supply chain of care." said Dr. Sharvil Patel, Managing Director of Zydus Lifesciences Limited. "Methylene blue is a cationic thiazine dye that necessitates specialised capabilities and expertise to develop and manufacture the product. The efforts of our team who have worked on the development, filing and manufacturing of Methylene Blue Injection reflects our ongoing commitment to bring complex generic products accessible to patients who need them the most.", he added.

Methylene Blue Injection is an oxidation-reduction agent indicated for the treatment of pediatric and adult patients with acquired methemoglobinemia. Methylene Blue Injection, 10mg/2ml and 50mg/5ml had an annual sale of approximately USD 73.4 mn in the United States (IQVIA MAT Oct-2023).

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global life sciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 25000 people worldwide and is driven by its mission to unlock new possibilities in life sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. For more details visit www.zyduslife.com.

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