FDA Approves New Drug Application for 3M DuraPrep Surgical Solution

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- Approval Reinforces 3M DuraPrep Surgical Solution’s Safety and Efficacy as a Leading Skin Preparation Solution in the United States -

ST. PAUL, Minn.--(BUSINESS WIRE)--3M announced today U.S. Food and Drug Administration (FDA) approval of New Drug Application (NDA) 21-586 for 3M DuraPrep surgical solution (iodine povacrylex [0.7% available iodine] and isopropyl alcohol, 74%w/w) patient preoperative skin preparation. DuraPrep surgical solution has been available and used in more than 20 million preoperative patient skin preparation procedures since 1988.

In 1994, the FDA published the Tentative Final Monograph for Healthcare Antiseptic Drug Products by which it regulates health care antiseptic solutions. In this monograph, FDA limited the allowable form of iodophor used in patient preoperative skin preparations to povidone iodine. Because DuraPrep surgical solution uses a proprietary, film-forming iodine acrylate copolymer that differentiates it from treatments based on traditional povidone-iodine, this monograph, when finalized, is not expected to cover DuraPrep surgical solution. After discussions with the FDA about the unique iodine acrylate copolymer in DuraPrep surgical solution, 3M decided to file a NDA to seek formal approval from the FDA for this novel compound.

"As the market leader, we are pleased to receive FDA approval of DuraPrep surgical solution and believe that this will only enhance the confidence that clinicians have in the product that they have relied on for the last 18 years," said James Ingebrand, infection prevention business director, 3M Health Care. "We are proud to continue providing technologies that ensure our commitment to patient safety and infection control."

As part of the NDA, 3M submitted data from six pivotal efficacy studies and two pivotal safety studies. Three studies involving healthy volunteers tested DuraPrep surgical solution's efficacy on the abdomen (n = 106) and groin (n = 196). All three studies showed DuraPrep surgical solution was either generally equivalent or superior to Hibiclens cleanser, a chlorhexidine gluconate (CHG) aqueous-based antimicrobial solution.

"As a surgeon who has relied on DuraPrep surgical solution for the last two decades, I believe that the endorsement of DuraPrep surgical solution's clinical data by the FDA strengthens an already highly effective and dependable product," said Richard Evans, M.D., director of the Center for Hip and Knee Surgery, University of Arkansas for Medical Sciences. "It is vital today to take all necessary steps to prevent infection during surgery, and 3M has consistently provided innovative products that meet the needs of surgeons and health-care professionals working to minimize the risk of infection."

In addition, 3M has received a United States Adopted Name Council (USAN) approved chemical name, iodine povacrylex, for the proprietary iodine acrylate copolymer in DuraPrep surgical solution. This unique chemical name clearly differentiates the iodophor used in DuraPrep surgical solution from povidone-iodine (PVP-I) formulations. Iodine povacrylex provides several benefits, including superior resistance to removal by blood and irrigating solutions compared to non-copolymer formulations; continued antimicrobial activity after blood and saline exposure; and excellent drape adhesion compared to non-copolymer formulations, such as PVP-I or CHG.

About DuraPrep Surgical Solution

DuraPrep surgical solution contains two active ingredients, isopropyl alcohol (74% w/w) for fast kill and iodine povacrylex (0.7% available iodine) for persistence. The superior performance of DuraPrep surgical solution can be attributed to its unique film-forming properties which enable it to dry to a water-resistant film, enhancing drape adhesion, optimizing the persistent effects of iodine and resisting wash-off. The product's unique applicator design provides ease of use and minimizes risk of contamination during the prepping procedure.

Under simulated surgical conditions, DuraPrep surgical solution resisted removal by blood and saline compared to Betadine scrub and paint. DuraPrep surgical solution keeps bacterial counts low for up to 24 hours and improves drape adhesion which is essential in reducing the risk of infection during high-risk surgeries, including cardiac, orthopedic and neurosurgery. Clinicians are provided with detailed information on how to use DuraPrep surgical solution safely and effectively, even in surgical cases requiring electrocautery.

3M is committed to infection prevention and DuraPrep surgical solution is the second NDA drug product in 3M's Medical Division to receive FDA approval joining 3M Avagard (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w) surgical and health care personnel hand antiseptic with moisturizers.

About 3M Health Care
Since inventing Ioban incise antimicrobial surgical drapes more than 30 years ago, 3M has been a worldwide leader in developing health care products and services that address infection control. 3M Health Care is dedicated to improving the practice, delivery and outcome of patient care and is a leading provider of solutions for medical, dental, pharmaceutical and health information systems markets.

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