



GE HealthCare Expands Contrast Media Portfolio with Launch of MRI Agent Pixxoscan (gadobutrol)

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- The launch of Pixxoscan expands GE HealthCare's portfolio of Magnetic Resonance Imaging (MRI) contrast agents, now offering two leading macrocyclic molecules to customers - Clariscan (gadoteric acid) and Pixxoscan (gadobutrol)
- Pixxoscan has the same active substance (gadobutrol) and the same qualitative and quantitative composition as the reference product, Gadovist®
- The availability of Pixxoscan will give radiology departments greater access to agents supporting a broad range of MRI procedures, helping them in personalizing care for patients.

CHALFONT ST GILES, England--(BUSINESS WIRE)--Apr. 27, 2023-- GE HealthCare has today announced the launch of Pixxoscan (gadobutrol), its macrocyclic, non-ionic Magnetic Resonance Imaging (MRI) gadolinium-based contrast agent (GBCA). Pixxoscan has been reviewed using a regulatory decentralized procedure (DCP) with marketing authorization already in place in Austria and pending approval, will be introduced to a number of European countries in 2023.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20230426005641/en/>



Enhanced Magnetic Resonance (MR) procedure with cardiac scan images (Photo: Business Wire)

It has been reviewed as having the same qualitative and quantitative composition in active substance and excipients, and the same pharmaceutical form, as the reference product, Gadovist.

Pixxoscan facilitates visualization of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue. In line with the reference product, Gadovist, Pixxoscan (gadobutrol) is indicated for use in adults, adolescents, and children of all ages (including term neonates) for contrast enhancement in cranial and spinal MRI and magnetic resonance angiography. It is also indicated for whole body imaging, including liver and kidneys in patients with high suspicion or evidence of having focal lesions to classify them as benign or malignant.

Gadobutrol has a high relaxivity which helps enhance detection, delineation and characterization in MRI across its range of indications. It is also formulated at twice the concentration of gadolinium ions, reducing injection volume by half compared to other GBCAs, providing a tighter bolus. Its cage-like macrocyclic chelate, which encloses the gadolinium, provides high kinetic stability.

Pixxoscan adds to GE HealthCare's MRI contrast media portfolio which includes macrocyclic Clariscan (gadoteric acid) as well as Rapiscan, used in stress cardiac MR to aid diagnosis of coronary artery disease and offering an alternative for patients who cannot exercise. The availability of Pixxoscan will give radiology departments greater access to agents supporting a broad range of MRI procedures, helping them in personalizing care for patients.

Dr Gianluca Pontone, Director of Perioperative Cardiology and Cardiovascular Imaging Department, Monzino Cardiology Center, Milan, Italy, said: "GE HealthCare continues to expand its range of products and Pixxoscan sitting alongside cardiac stress agent, Rapiscan, is welcome news. This gives me, as a cardiologist, the products I need to aid in making timely diagnoses for patients with suspected coronary artery disease."

Mark Hibberd, Chief Medical Officer, GE HealthCare Pharmaceutical Diagnostics, said: "This extension to our portfolio means, we will be able to offer two leading macrocyclic molecules – Clariscan (gadoteric acid) and Pixxoscan (gadobutrol) - to our customers in a number of European countries, offering radiology departments even more choice to suit their diagnostic needs. We continue to innovate and invest in our contrast media portfolio to deliver for healthcare professionals and patients and to meet future demand."

Pixxoscan (gadobutrol) offers a wide range of packaging encompassing glass vials, ready-assembled plastic prefilled syringes and larger volume +PLUSPAK polypropylene bottles. GE HealthCare's +PLUSPAK plastic packaging, using flip-top lids, helps eliminate risk of, and downtime from, broken glass and ring-pull injuries. +PLUSPAK also provides more choice for customers and helps them reduce their costs and environmental impact.

As with all GE HealthCare contrast agents, Pixxoscan will be produced in compliance with current Good Manufacturing Practices (cGMP) - with rigorous testing at our primary and secondary manufacturing sites in Norway to ensure high quality. Once approved, it will then be labelled and packed for onward shipping via our standard distribution network to local markets.

GE HealthCare's Pharmaceutical Diagnostics unit is a global leader in imaging agents used to support around 100 million procedures per year globally, equivalent to three patient procedures every second. For more than 40 years, GE HealthCare imaging agents have been routinely used across MRI, X-ray/CT and ultrasound to enhance clinical images and support diagnosis.

About GE HealthCare Technologies Inc.

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 100 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from diagnosis, to therapy, to monitoring. We are an \$18.3 billion business with 50,000 employees working to create a world where healthcare has no limits.

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