


Piramal Imaging SA
NDA 204677

Labeling

Neuraceq 30 mL Vial Label

Drug Product Vial Label

NDC 54828-001-30	30 mL Multiple-Dose Vial	CAUTION  RADIOACTIVE MATERIAL
Neuraceq™ Florbetaben F18 injection	Sterile Non-Pyrogenic Rx ONLY	
Activity at *EOS _____ MBq (_____ mCi) in _____ mL at _____:_____ on _____.	Volume: 29 mL	
Expiration Date/Time _____/_____/_____	Concentration at *EOS _____ mCi/mL	
(Expires 10 Hours after *EOS)		
Diagnostic - For Intravenous Use Only		
Batch No.: _____	Date: _____	
Each mL contains up to 3 mcg of florbetaben and 50 - 5000 MBq/mL (1.4 - 135 mCi/mL) florbetaben F18 at *EOS, 4.4 mg ascorbic acid, 118 mg ethanol, 200 mg macrogol (PEG400), 28.8 mg sodium ascorbate, 677.5 mg water for injection. *EOS - End of Synthesis		
Store at room temperature 25°C (77°F); excursions permitted to 2°C to 42°C (36°F - 108°F). Store upright. Do not use if it is cloudy or contains particulate matter.		
Manufactured by Zevacor Pharma, Inc., 21000 Atlantic Blvd., Ste. 730, Dulles, VA 20166 for Piramal Imaging SA		

SPF-061-V03


Confidential

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Labeling

Neuraceq Shield Label

Drug Product Shield Label

NDC 54828-001-30	30 mL Multiple-Dose Vial	CAUTION
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Batch No.: _____ Date: _____		
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