

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 416, 8 Januari 2026

Products approved for additional indication (DCA 415 – 8 January 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)						
1.	<p>BOMNIPAQUE INJ 300MG I/ML</p> <p>[Iohexol 647mg/ml (equivalent to 300mg I/ml)]</p> <p>OMNIPAQUE INJ 350MG I/ML</p> <p>[Iohexol 755mg/ml (equivalent to 350mg I/ml)]</p>	<p>INDICATION :</p> <p>Contrast-enhanced mammography (CEM) in adult women to evaluate and detect known or suspect lesions in the breast,</p> <p>– as an adjunct to mammography (with or without ultrasound) or</p> <p>– as an alternative to magnetic resonance imaging (MRI) when MRI is contraindicated or not available.</p> <p>POSOLOGY :</p> <p>Guidelines for Intravenous use:</p> <table><tr><th>Indication/ Investigation</th><th>Concentration</th><th>Volume</th></tr><tr><td>Contrast-enhanced mammography (CEM)</td><td>300 mg I/ml or 350 mg I/ml</td><td>1.5 mL/kgbw 1.3 mL/kgbw</td></tr></table>	Indication/ Investigation	Concentration	Volume	Contrast-enhanced mammography (CEM)	300 mg I/ml or 350 mg I/ml	1.5 mL/kgbw 1.3 mL/kgbw	<p>PHARMAFORTE (MALAYSIA) SDN. BHD.</p> <p>No. 2, Jalan PJU 3/49, Sunway Damansara, 47810 Petaling Jaya, Selangor.</p>
Indication/ Investigation	Concentration	Volume							
Contrast-enhanced mammography (CEM)	300 mg I/ml or 350 mg I/ml	1.5 mL/kgbw 1.3 mL/kgbw							