

**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 [Iohexol 647mg/ml (equivalent to 300mg I/ml)]</p> <p>OMNIPAQUE INJ 350MG I/ML [Iohexol 755mg/ml (equivalent to 350mg I/ml)]</p>	<p><b>INDICATION :</b></p> <p>Contrast-enhanced mammography (CEM) in adult women to evaluate and detect known or suspect lesions in the breast,</p> <ul style="list-style-type: none"> <li>– as an adjunct to mammography (with or without ultrasound) or</li> <li>– as an alternative to magnetic resonance imaging (MRI) when MRI is contraindicated or not available.</li> </ul> <p><b>POSOLOGY :</b></p> <p>Guidelines for Intravenous use:</p> <table border="1"> <thead> <tr> <th>Indication/ Investigation</th> <th>Concentration</th> <th>Volume</th> </tr> </thead> <tbody> <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> </tbody> </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><b>PHARMAFORTE (MALAYSIA) SDN. BHD.</b> 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							