

**Maklumat tambahan indikasi untuk upload pada laman web  
Year 2015**

**Products Approved For Additional Indication (DCA 289 – 29 Jun 2015)**

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 <b>AVASTIN INJECTION 25 MG/ML</b> [Bevacizumab 25mg/ml]	<p>➤ Indication:</p> <p><u>Cervical Cancer</u> <i>Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.</i></p> <p>➤ Posology:</p> <p><u>Cervical Cancer</u> <i>Avastin is administered in combination with one of the following chemotherapy regimens: Paclitaxel and cisplatin or paclitaxel and topotecan. The recommended dose of Avastin is 15mg/kg of body weight given once every 3 weeks as an intravenous infusion. It is recommended that Avastin treatment be continued until progression of the underlying disease.</i></p>	<p><b>ROCHE (MALAYSIA) SDN BHD</b> Level 21, The Pinnacle, Persiaran Lagoon Bandar Sunway, 47500 Subang Jaya, Selangor</p>
2.	2.2 <b>MULTIHANCE INJECTION SOLUTION</b> [Gadobenate dimeglumine]	<p>➤ Indication:</p> <p><i>MultiHance® is a paramagnetic contrast agent for use in diagnostic magnetic resonance imaging (MRI) indicated for:</i></p> <ul style="list-style-type: none"> <li><i>MRI of the breast, for the detection of malignant lesions in patients where breast cancer is known or suspected on the basis of previous mammography or ultrasound results.</i></li> </ul> <p>➤ Posology:</p> <p><u>MRI of the breast:</u> <i>The recommended dose of MultiHance in adult patients is 0.1mmol/kg body weight. This corresponds to 0.2mL/kg of the 0.5M solution.</i></p> <p><u>Post-contrast imaging acquisition:</u></p>	<p><b>SALVO HEALTHCARE SDN BHD</b> 11-4, Jalan USJ 9/5Q Subang Business Centre 47620 Subang Jaya, Selangor</p>

Liver	<u>Dynamic imaging:</u>	<u>Immediately following bolus injection.</u>
	<u>Delayed imaging:</u>	Between 40 and 120 minutes following the injection, depending on the individual imaging needs.
Brain and Spine	Up to 60 minutes after the administration.	
MRA	Immediately after the administration, with scan delay calculated on the basis of test bolus or automatic bolus detection technique. If an automatic contrast detection pulse sequence is not used for bolus timing, then a test bolus injection ≤2mL of the agent should be used to calculate the appropriate scan delay.	
Breast	T1-weighted, dynamic acquisition immediately following bolus injection and then repeated at 2, 4, 6 and 8 minutes.	

### Special Populations

#### Impaired renal function

If use of MultiHance® cannot be avoided, the dose should not exceed 0.1mmol/kg body weight when used for MR of the brain and spine, MR-angiography or breast MRI and should not exceed 0.05mmol/kg body weight when used for MR of the liver. More than one dose should not be used during a scan. Because of the lack of information on repeated administration, MultiHance® injections should not be repeated unless the interval between injections is at least 7 days.

#### Paediatric population

Use for MRI of the liver, MRI of the breast and MRA is not recommended in children less than 18 years of age.