



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 January 2021

EMA/217399/2021

Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: gadobenic acid

Procedure no.: PSUSA/00001500/202004



| <b>Product Name (in authorisation country)</b>                    | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|-------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| MultiHance 0,5 M oldatos injekció                                 | not available                       | OGYI-T-8432/01                       | BRACCO IMAGING S.P.A.                     | HU                                              |
| MultiHance 0,5 M oldatos injekció                                 | not available                       | OGYI-T-8432/02                       | BRACCO IMAGING S.P.A.                     | HU                                              |
| MultiHance 0,5 M oldatos injekció                                 | not available                       | OGYI-T-8432/03                       | BRACCO IMAGING S.P.A.                     | HU                                              |
| MultiHance 0,5 M oldatos injekció                                 | not available                       | OGYI-T-8432/04                       | BRACCO IMAGING S.P.A.                     | HU                                              |
| MultiHance 529 mg/ml oldatos injekció eloretöltött fecskendoben   | not available                       | OGYI-T-8432/05                       | BRACCO IMAGING S.P.A.                     | HU                                              |
| MultiHance 529 mg/ml oldatos injekció eloretöltött fecskendoben   | not available                       | OGYI-T-8432/06                       | BRACCO IMAGING S.P.A.                     | HU                                              |
| MultiHance 529 mg/ml oldatos injekció eloretöltött fecskendoben   | not available                       | OGYI-T-8432/07                       | BRACCO IMAGING S.P.A.                     | HU                                              |
| MultiHance 529 mg/ml solução injectável                           | not available                       | 3256583                              | BRACCO IMAGING S.P.A.                     | PT                                              |
| MultiHance 529 mg/ml solução injectável                           | not available                       | 3256682                              | BRACCO IMAGING S.P.A.                     | PT                                              |
| MultiHance 529 mg/ml solução injectável                           | not available                       | 3256781                              | BRACCO IMAGING S.P.A.                     | PT                                              |
| MultiHance 529 mg/ml solução injectável                           | not available                       | 3256880                              | BRACCO IMAGING S.P.A.                     | PT                                              |
| MultiHance, 0.5M solution for injection                           | DE/H/5991/001                       | PA1826/001/001                       | BRACCO IMAGING S.P.A.                     | IE                                              |
| MultiHance 529 mg/ml solution for injection in pre-filled syringe | DE/H/5991/002                       | PA1826/001/002                       | BRACCO IMAGING S.P.A.                     | IE                                              |
| MultiHance 0,5 M - Injektionslösung                               | DE/H/5991/001                       | 1-22773                              | BRACCO IMAGING S.P.A.                     | AT                                              |
| MultiHance 0,5 mmol/ml Injektionslösung in                        | DE/H/5991/002                       | 1-27519                              | BRACCO IMAGING S.P.A.                     | AT                                              |

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| Fertigspritze                                                                       |                              |                               |                                    |                                          |
| MultiHance, injektionsvæske, opløsning                                              | DE/H/5991/001                | 19317                         | BRACCO IMAGING S.P.A.              | DK                                       |
| MultiHance, injektionsvæske, opløsning i fyldt injektionssprøjte                    | DE/H/5991/002                | 40645                         | BRACCO IMAGING S.P.A.              | DK                                       |
| MultiHance 334 mg/ml (0,5 M) injektioneste, liuos                                   | DE/H/5991/001                | 13152                         | BRACCO IMAGING S.P.A.              | FI                                       |
| MultiHance 334 mg/ml (0,5 mmol/ml) injektioneste, liuos esitäytetyssä ruiskussa     | DE/H/5991/002                | 23183                         | BRACCO IMAGING S.P.A.              | FI                                       |
| MultiHance 334 mg/ml (0,5 mmol/ml) injeksjonsvæske                                  | DE/H/5991/001                | 03-2358                       | BRACCO IMAGING S.P.A.              | NO                                       |
| MultiHance 334 mg/ml (0,5 mmol/ml) injeksjonsvæske, oppløsning i ferdigfylt sprøyte | DE/H/5991/002                | 07-4726                       | BRACCO IMAGING S.P.A.              | NO                                       |
| MultiHance 334 mg/ml (0,5 mmol/ml) injektionsvätsk                                  | DE/H/5991/001                | 14042                         | BRACCO IMAGING S.P.A.              | SE                                       |
| MultiHance 334 mg/ml (0,5 mmol/ml) injektionsvätska, lösning, förfylld spruta       | DE/H/5991/002                | 25060                         | BRACCO IMAGING S.P.A.              | SE                                       |
| MULTIHANCE 0,5 M soluzione iniettabile                                              | DE/H/5991/001                | 034152013                     | BRACCO IMAGING S.P.A.              | IT                                       |
| MULTIHANCE 0,5 M soluzione iniettabile                                              | DE/H/5991/001                | 034152025                     | BRACCO IMAGING S.P.A.              | IT                                       |

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| MULTIHANCE 0,5 M<br>soluzione iniettabile                                    | DE/H/5991/001                | 034152037                     | BRACCO IMAGING S.P.A.              | IT                                       |
| MULTIHANCE 0,5 M<br>soluzione iniettabile                                    | DE/H/5991/001                | 034152049                     | BRACCO IMAGING S.P.A.              | IT                                       |
| MULTIHANCE 529 mg/ml<br>soluzione iniettabile in<br>siringhe pre-riempite.   | DE/H/5991/002                | 034152052                     | BRACCO IMAGING S.P.A.              | IT                                       |
| MULTIHANCE 529 mg/ml<br>soluzione iniettabile in<br>siringhe pre-riempite.   | DE/H/5991/002                | 034152064                     | BRACCO IMAGING S.P.A.              | IT                                       |
| MULTIHANCE 529 mg/ml<br>soluzione iniettabile in<br>siringhe pre-riempite.   | DE/H/5991/002                | 034152076                     | BRACCO IMAGING S.P.A.              | IT                                       |
| MultiHance, 0.5M<br>εξέσιμι δόζημα                                           | DE/H/5991/001                | 41661/23-6-2015               | BRACCO IMAGING S.P.A.              | GR                                       |
| MultiHance 529 mg/ml<br>ενέσιμο διάλυμα σε<br>προγεμισμένη                   | DE/H/5991/002                | 41662/23-6-2015               | BRACCO IMAGING S.P.A.              | GR                                       |
| MultiHance 0,5<br>mmol/mL, solution<br>injectable                            | DE/H/5991/001                | 3400930031278                 | BRACCO IMAGING FRANCE              | FR                                       |
| MultiHance 0,5<br>mmol/mL, solution<br>injectable                            | DE/H/5991/001                | 3400930031292                 | BRACCO IMAGING FRANCE              | FR                                       |
| MultiHance 0,5<br>mmol/mL, solution<br>injectable en seringue<br>pré-remplie | DE/H/5991/002                | 3400930031308                 | BRACCO IMAGING FRANCE              | FR                                       |
| MultiHance 0,5<br>mmol/mL, solution<br>injectable en seringue<br>pré-remplie | DE/H/5991/002                | 3400930031315                 | BRACCO IMAGING FRANCE              | FR                                       |
| MultiHance 0,5<br>mmol/mL, solution                                          | DE/H/5991/002                | 3400930031322                 | BRACCO IMAGING FRANCE              | FR                                       |

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| injectable en seringue pré-remplie                                    |                                     |                                      |                                           |                                                 |
| MultiHance 0,5 mmol/mL, solution injectable en seringue pré-remplie   | DE/H/5991/002                       | 3400930031339                        | BRACCO IMAGING FRANCE                     | FR                                              |
| MultiHance, 0.5 M oplossing voor injectie                             | DE/H/5991/001                       | BE199963                             | BRACCO IMAGING DEUTSCHLAND GMBH           | BE                                              |
| MultiHance, 0.5 M oplossing voor injectie                             | DE/H/5991/001                       | BE199972                             | BRACCO IMAGING DEUTSCHLAND GMBH           | BE                                              |
| MultiHance, 0.5 M oplossing voor injectie                             | DE/H/5991/001                       | BE199981                             | BRACCO IMAGING DEUTSCHLAND GMBH           | BE                                              |
| MultiHance, 0.5 M oplossing voor injectie                             | DE/H/5991/001                       | BE199997                             | BRACCO IMAGING DEUTSCHLAND GMBH           | BE                                              |
| MultiHance 529 mg/ml oplossing voor injectie in een voorgevulde spuit | DE/H/5991/002                       | BE324877                             | BRACCO IMAGING DEUTSCHLAND GMBH           | BE                                              |
| MultiHance 529 mg/ml oplossing voor injectie in een voorgevulde spuit | DE/H/5991/002                       | BE324886                             | BRACCO IMAGING DEUTSCHLAND GMBH           | BE                                              |
| MultiHance 529 mg/ml oplossing voor injectie in een voorgevulde spuit | DE/H/5991/002                       | BE324895                             | BRACCO IMAGING DEUTSCHLAND GMBH           | BE                                              |
| MultiHance, 0,5 M Injektionslösung                                    | DE/H/5991/001                       | 42393.00.00                          | BRACCO IMAGING DEUTSCHLAND GMBH           | DE                                              |
| MultiHance 0,5 mmol/ml Injektionslösung in Fertigspritze              | DE/H/5991/002                       | 68585.00.00                          | BRACCO IMAGING DEUTSCHLAND GMBH           | DE                                              |
| MultiHance 0,5 mmol/mL, solution injectable en seringue pré-remplie   | DE/H/5991/002                       | 3400938879667                        | BRACCO IMAGING FRANCE                     | FR                                              |
| MultiHance 0,5 mmol/mL, solution                                      | DE/H/5991/002                       | 3400938879728                        | BRACCO IMAGING FRANCE                     | FR                                              |

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| injectable en seringue pré-remplie                                   |                                     |                                      |                                           |                                                 |
| MultiHance 0,5 mmol/mL, solution injectable en seringue pré-remplie  | DE/H/5991/002                       | 3400938879896                        | BRACCO IMAGING FRANCE                     | FR                                              |
| MultiHance 529 mg/ml solución inyectable                             | DE/H/5991/001                       | 66.373                               | BRACCO IMAGING S.P.A.                     | ES                                              |
| MultiHance 529 mg/ml solución inyectable en jeringa precargada       | DE/H/5991/002                       | 71.048                               | BRACCO IMAGING S.P.A.                     | ES                                              |
| MultiHance 529 mg/ml solution injectable en seringue préremplie      | DE/H/5991/002                       | 0953/08120044                        | BRACCO IMAGING DEUTSCHLAND GMBH           | LU                                              |
| MultiHance 0,5 mmol/ml solution injectable                           | DE/H/5991/001                       | 0953/98100004                        | BRACCO IMAGING DEUTSCHLAND GMBH           | LU                                              |
| MultiHance, oplossing voor injectie 529 mg/ml                        | DE/H/5991/001                       | RVG22324                             | BRACCO IMAGING DEUTSCHLAND GMBH           | NL                                              |
| MultiHance 529 mg/ml oplossing voor injectie in voorgevulde spuit    | DE/H/5991/002                       | RVG35016                             | BRACCO IMAGING DEUTSCHLAND GMBH           | NL                                              |
| MULTIHANCE 0,5 M soluzione iniettabile                               | DE/H/5991/001                       | 034152088                            | BRACCO IMAGING S.P.A.                     | IT                                              |
| MULTIHANCE 0,5 M soluzione iniettabile                               | DE/H/5991/001                       | 034152090                            | BRACCO IMAGING S.P.A.                     | IT                                              |
| MULTIHANCE 529 mg/ml soluzione iniettabile in siringhe pre-riempite. | DE/H/5991/002                       | 034152102                            | BRACCO IMAGING S.P.A.                     | IT                                              |
| MULTIHANCE 529 mg/ml soluzione iniettabile in siringhe pre-riempite. | DE/H/5991/002                       | 034152114                            | BRACCO IMAGING S.P.A.                     | IT                                              |
| MULTIHANCE 529 mg/ml soluzione iniettabile in siringhe pre-riempite. | DE/H/5991/002                       | 034152126                            | BRACCO IMAGING S.P.A.                     | IT                                              |

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| MULTIHANCE 529 mg/ml soluzione iniettabile in siringhe pre-riempite.             | DE/H/5991/002                       | 034152138                            | BRACCO IMAGING S.P.A.                     | IT                                              |
| MultiHance 0,5 mmol/mL, solution injectable                                      | DE/H/5991/001                       | 3400934741128                        | BRACCO IMAGING FRANCE                     | FR                                              |
| MultiHance 0,5 mmol/mL, solution injectable                                      | DE/H/5991/001                       | 3400934741296                        | BRACCO IMAGING FRANCE                     | FR                                              |
| MultiHance 0,5 mmol/mL, solution injectable                                      | DE/H/5991/001                       | 3400934741357                        | BRACCO IMAGING FRANCE                     | FR                                              |
| MultiHance 0,5 mmol/mL, solution injectable                                      | DE/H/5991/001                       | 3400934741418                        | BRACCO IMAGING FRANCE                     | FR                                              |
| MultiHance, 0.5 M solution for injection                                         | DE/H/5991/001                       | PL 18920/0039                        | BRACCO UK LTD                             | UK                                              |
| MultiHance 529 mg/ml solution for injection in pre-filled syringe                | DE/H/5991/002                       | PL 18920/0040                        | BRACCO UK LTD                             | UK                                              |
| MultiHance, 529 mg/ml (0,5 mmol/ml), roztwór do wstrzykiwań dożylnych            | not available                       | 9174                                 | BRACCO IMAGING DEUTSCHLAND GMBH           | PL                                              |
| MultiHance, 529 mg/ml (0,5 mmol/ml), roztwór do wstrzykiwań w ampułko-strzykawce | not available                       | 24138                                | BRACCO IMAGING DEUTSCHLAND GMBH           | PL                                              |
| MultiHance 0,5 mmol/ml otopina za iniekciju                                      | not available                       | HR-H-872900882                       | BRACCO IMAGING S.P.A.                     | HR                                              |
| MultiHance 529 mg/ml soluție injectabilă                                         | not available                       | 11764/2019/01                        | BRACCO IMAGING S.P.A.                     | RO                                              |
| MultiHance 529 mg/ml soluție injectabilă                                         | not available                       | 11764/2019/02                        | BRACCO IMAGING S.P.A.                     | RO                                              |

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| MultiHance 529 mg/ml<br>solučie injectabilă                                   | not available                       | 11764/2019/03                        | BRACCO IMAGING S.P.A.                     | RO                                              |
| MultiHance 529 mg/ml<br>solučie injectabilă                                   | not available                       | 11764/2019/04                        | BRACCO IMAGING S.P.A.                     | RO                                              |
| MultiHance 0,5 mmol/ml<br>raztopina za injiciranje                            | not available                       | H/02/01067/001                       | BRACCO IMAGING S.P.A.                     | SI                                              |
| MultiHance 0,5 mmol/ml<br>raztopina za injiciranje                            | not available                       | H/02/01067/002                       | BRACCO IMAGING S.P.A.                     | SI                                              |
| MultiHance 0,5 mmol/ml<br>raztopina za injiciranje                            | not available                       | H/02/01067/003                       | BRACCO IMAGING S.P.A.                     | SI                                              |
| MultiHance 0,5 mmol/ml<br>raztopina za injiciranje                            | not available                       | H/02/01067/004                       | BRACCO IMAGING S.P.A.                     | SI                                              |
| MultiHance 529 mg/ml<br>injekční roztok v<br>předplněné injekční<br>stříkačce | not available                       | 48/227/14-C                          | BRACCO IMAGING<br>DEUTSCHLAND GMBH        | CZ                                              |
| MultiHance 529 mg/ml<br>injekční roztok                                       | not available                       | 48/495/00-C                          | BRACCO IMAGING<br>DEUTSCHLAND GMBH        | CZ                                              |
| MultiHance XL, 0,5 M,<br>Injektionslösung                                     | not available                       | 55845.00.00                          | BRACCO IMAGING<br>DEUTSCHLAND GMBH        | DE                                              |