



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 January 2021

EMA/217490/2021

Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: gadoteridol

Procedure no.: PSUSA/00001507/202004



<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>
ProHance 279,3 mg/ml soluzione per infusione	not available	029055011	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml soluzione per infusione	not available	029055023	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml soluzione per infusione	not available	029055035	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml soluzione per infusione	not available	029055047	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml soluzione per infusione	not available	029055050	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml soluzione per infusione	not available	029055062	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml soluzione per infusione	not available	029055074	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml soluzione per infusione	not available	029055086	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml soluzione per infusione	not available	029055124	BRACCO IMAGING ITALIA SRL	IT
ProHance 279,3 mg/ml injekční roztok	not available	48/151/00-A/C	BRACCO IMAGING DEUTSCHLAND GMBH	CZ
ProHance 279,3 mg/ml injekční roztok v předplněné injekční stříkačce	not available	48/151/00-B/C	BRACCO IMAGING DEUTSCHLAND GMBH	CZ
ProHance 279,3 mg/ml injektioneste, liuos	not available	11428	BRACCO INTERNATIONAL BV	FI
ProHance 279,3 mg/ml injektioneste, liuos, esitäytetty ruisku	not available	36147	BRACCO INTERNATIONAL BV	FI
ProHance, 279,3 mg/ml (0,5 mmol/ml), roztwór do wstrzykiwań	not available	8320	BRACCO IMAGING DEUTSCHLAND GMBH	PL
ProHance, injektionsvæske,	not available	15357	BRACCO INTERNATIONAL BV	DK

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opløsning				
PROHANCE, 279,3 mg/ml, solution injectable	not available	0953/05088286	BRACCO IMAGING DEUTSCHLAND GMBH	LU
PROHANCE 0,5 mmol/mL, solution injectable	FR/H/0646/01-02/MR	NL 19115	BRACCO IMAGING FRANCE	FR
PROHANCE 0,5 mmol/mL, solution injectable en seringue pré-remplie	FR/H/0646/01-02/MR	NL 21915	BRACCO IMAGING FRANCE	FR
Prohance 0,5 mmol/ml, süstelahus	FR/H/0646/001	988819	BRACCO IMAGING S.P.A.	EE
Prohance 0,5 mmol/ml, süstelahus süstlis	FR/H/0646/002	988919	BRACCO IMAGING S.P.A.	EE
ProHance 0,5 mmol/ml injekcinis tirpalas	FR/H/0646/001	LT/1/19/4401/001	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas	FR/H/0646/001	LT/1/19/4401/002	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas	FR/H/0646/001	LT/1/19/4401/003	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas	FR/H/0646/001	LT/1/19/4401/004	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas	FR/H/0646/001	LT/1/19/4401/005	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas	FR/H/0646/001	LT/1/19/4401/006	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	FR/H/0646/002	LT/1/19/4402/001	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	FR/H/0646/002	LT/1/19/4402/002	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml	FR/H/0646/002	LT/1/19/4402/003	BRACCO IMAGING S.P.A.	LT

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injekcinis tirpalas užpildytame švirkšte				
ProHance 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	FR/H/0646/002	LT/1/19/4402/004	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	FR/H/0646/002	LT/1/19/4402/005	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	FR/H/0646/002	LT/1/19/4402/006	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	FR/H/0646/002	LT/1/19/4402/007	BRACCO IMAGING S.P.A.	LT
ProHance 0,5 mmol/ml otopina za injekciju	FR/H/0646/001	HR-H-668102412	BRACCO IMAGING S.P.A.	HR
ProHance 0,5 mmol/ml otopina za injekciju u napunjenoj štrcaljki	FR/H/0646/002	HR-H-986593014	BRACCO IMAGING S.P.A.	HR
ProHance 0,5 mmol/ml soluție injectabilă	FR/H/0646/001	11933/2019/01	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă în seringă preumplută	FR/H/0646/001	11934/2019/01	BRACCO IMAGING S.P.A.	RO
Prohance 0,5 mmol/ml šķīdums injekcijām	FR/H/0646/001	19-0089	BRACCO IMAGING S.P.A.	LV
Prohance 0,5 mmol/ml šķīdums injekcijām pilnšļircē	FR/H/0646/002	19-0090	BRACCO IMAGING S.P.A.	LV
ProHance 0,5 mmol/ml soluție injectabilă	FR/H/0646/001	11933/2019/02	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă	FR/H/0646/001	11933/2019/03	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml	FR/H/0646/001	11933/2019/04	BRACCO IMAGING S.P.A.	RO

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soluție injectabilă				
ProHance 0,5 mmol/ml soluție injectabilă	FR/H/0646/001	11933/2019/05	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă	FR/H/0646/001	11933/2019/06	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă în seringă preumplută	FR/H/0646/002	11934/2019/02	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă în seringă preumplută	FR/H/0646/002	11934/2019/03	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă în seringă preumplută	FR/H/0646/002	11934/2019/04	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă în seringă preumplută	FR/H/0646/002	11934/2019/05	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă în seringă preumplută	FR/H/0646/002	11934/2019/06	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml soluție injectabilă în seringă preumplută	FR/H/0646/002	11934/2019/07	BRACCO IMAGING S.P.A.	RO
ProHance 0,5 mmol/ml oldatos injekció	FR/H/0646/001	OGYI-T-23577/01	BRACCO IMAGING S.P.A.	HU
ProHance 0,5 mmol/ml oldatos injekció	FR/H/0646/001	OGYI-T-23577/02	BRACCO IMAGING S.P.A.	HU
ProHance 0,5 mmol/ml oldatos injekció	FR/H/0646/001	OGYI-T-23577/03	BRACCO IMAGING S.P.A.	HU
ProHance 0,5 mmol/ml oldatos injekció	FR/H/0646/001	OGYI-T-23577/04	BRACCO IMAGING S.P.A.	HU
ProHance 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	FR/H/0646/002	OGYI-T-23577/05	BRACCO IMAGING S.P.A.	HU

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ProHance 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	FR/H/0646/002	OGYI-T-23577/06	BRACCO IMAGING S.P.A.	HU
ProHance 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	FR/H/0646/002	OGYI-T-23577/07	BRACCO IMAGING S.P.A.	HU
ProHance 0,5 mmol/ml raztopina za injiciranje	FR/H/0646/001	H/19/02643/001	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje	FR/H/0646/001	H/19/02643/002	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje	FR/H/0646/001	H/19/02643/003	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje	FR/H/0646/001	H/19/02643/004	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje	FR/H/0646/001	H/19/02643/005	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje	FR/H/0646/001	H/19/02643/006	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	FR/H/0646/002	H/19/02643/007	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	FR/H/0646/002	H/19/02643/008	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	FR/H/0646/002	H/19/02643/009	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	FR/H/0646/002	H/19/02643/010	BRACCO IMAGING S.P.A.	SI

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ProHance 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	FR/H/0646/002	H/19/02643/011	BRACCO IMAGING S.P.A.	SI
ProHance 0,5 mmol/ml, ενέσιμο διάλυμα	FR/H/0646/001	129037/11-11-2019	BRACCO IMAGING S.P.A.	GR
ProHance 0,5 mmol/ml, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα.	FR/H/0646/002	129038/11-11-2019	BRACCO IMAGING S.P.A.	GR
ProHance 0,5 mmol/mL, solução injetável	FR/H/0646/001	5787403	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável	FR/H/0646/001	5787411	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável	FR/H/0646/001	5787429	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável	FR/H/0646/001	5787437	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável	FR/H/0646/001	5787445	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável	FR/H/0646/001	5787452	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável em seringa pré-cheia	FR/H/0646/002	5787460	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável em seringa pré-cheia	FR/H/0646/002	5787478	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável em seringa pré-cheia	FR/H/0646/002	5787502	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável em seringa pré-cheia	FR/H/0646/002	5787510	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL,	FR/H/0646/002	5787528	BRACCO IMAGING S.P.A.	PT

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solução injetável em seringa pré-cheia				
ProHance 0,5 mmol/mL, solução injetável em seringa pré-cheia	FR/H/0646/002	5787536	BRACCO IMAGING S.P.A.	PT
ProHance 0,5 mmol/mL, solução injetável em seringa pré-cheia	FR/H/0646/002	5787544	BRACCO IMAGING S.P.A.	PT
ProHance 279.3 mg/ml, solution for injection	not available	PL 18920/0037	BRACCO UK LTD	UK
ProHance 279.3 mg/ml, solution for injection in prefilled syringes	not available	PL18920/0038	BRACCO UK LTD	UK
ProHance injekčný roztok	not available	48/0226/00-S	BRACCO IMAGING DEUTSCHLAND GMBH	SK
ProHance injekčný roztok	not available	48/0226/00-S	BRACCO IMAGING DEUTSCHLAND GMBH	SK
ProHance injekčný roztok	not available	48/0226/00-S	BRACCO IMAGING DEUTSCHLAND GMBH	SK
ProHance injekčný roztok	not available	48/0226/00-S	BRACCO IMAGING DEUTSCHLAND GMBH	SK
ProHance injekčný roztok	not available	48/0226/00-S	BRACCO IMAGING DEUTSCHLAND GMBH	SK
ProHance injekčný roztok	not available	48/0226/00-S	BRACCO IMAGING DEUTSCHLAND GMBH	SK
ProHance injekčný roztok	not available	48/0226/00-S	BRACCO IMAGING DEUTSCHLAND GMBH	SK
ProHance 279,3 mg/ml solución inyectable	not available	60.377	BRACCO INTERNATIONAL BV	ES
ProHance 279,3 mg/ml solución inyectable en jeringa precargada	not available	64.474	BRACCO INTERNATIONAL BV	ES
ProHance - Injektionslösung	not available	1-22234	BRACCO IMAGING S.P.A.	AT



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Prohance, oplossing voor injectie 279,3 mg/ml = 0,5 molair	not available	RVG16528	BRACCO IMAGING DEUTSCHLAND GMBH	NL
ProHance - Injektionslösung	not available	1-22234	BRACCO IMAGING S.P.A.	AT
ProHance 279,3 mg/ml injeksjonsvæske, oppløsning.	not available	95-2346	BRACCO INTERNATIONAL BV	NO
ProHance 279,3 mg/ml injeksjonsvæske, oppløsning	not available	18-12317	BRACCO INTERNATIONAL BV	NO
ProHance®, 0,5 M, Injektionslösung Gadoteridol	not available	46599.00.00	BRACCO IMAGING DEUTSCHLAND GMBH	DE
ProHance, 279,3 mg/ml, oplossing voor injectie	not available	BE430412	BRACCO IMAGING DEUTSCHLAND GMBH	BE
ProHance, 279,3 mg/ml, oplossing voor injectie	not available	BE199902	BRACCO IMAGING DEUTSCHLAND GMBH	BE
ProHance, 279,3 mg/ml, oplossing voor injectie	not available	BE199936	BRACCO IMAGING DEUTSCHLAND GMBH	BE
ProHance, 279,3 mg/ml, oplossing voor injectie	not available	BE199945	BRACCO IMAGING DEUTSCHLAND GMBH	BE
ProHance, 279,3 mg/ml, oplossing voor injectie	not available	BE199954	BRACCO IMAGING DEUTSCHLAND GMBH	BE
PROHANCE, 279,3 mg/ml, oplossing voor injectie	not available	BE274267	BRACCO IMAGING DEUTSCHLAND GMBH	BE
PROHANCE, 279,3 mg/ml, oplossing voor injectie	not available	BE521937	BRACCO IMAGING DEUTSCHLAND GMBH	BE
PROHANCE, 279,3 mg/ml, oplossing voor injectie	not available	BE521946	BRACCO IMAGING DEUTSCHLAND GMBH	BE
ProHance 279,3 mg/ml	not available	11795	BRACCO INTERNATIONAL BV	SE

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injektionsvätska, lösning				
ProHance 279,3 mg/ml injektionsvätska, lösning i förfylld spruta	not available	57970	BRACCO INTERNATIONAL BV	SE
ProHance, 279.3 mg/ml, Solution for Injection, 10 ml vial	not available	PA 0788/001/002	BRACCO INTERNATIONAL BV	IE
ProHance, 279.3 mg/ml, Solution for Injection, 15 ml vial	not available	PA 0788/001/003	BRACCO INTERNATIONAL BV	IE
ProHance, 279.3 mg/ml, Solution for Injection, 20 ml vial	not available	PA 0788/001/004	BRACCO INTERNATIONAL BV	IE