



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 January 2022
EMA/PRAC/14996/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance: pamidronate

Procedure No.: PSUSA/00002269/202105



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Pamidronate Disodium 3mg/ml Concentrate for Solution for Infusion	not available	PL 11311/0217	TILLOMED LABORATORIES LTD	XI
Pamidronate Disodium 3mg/ml Concentrate for Solution for Infusion	not available	PL 11311/0218	TILLOMED LABORATORIES LTD	XI
Pamidronate Disodium 6mg/ml Concentrate for Solution for Infusion	not available	PL 11311/0219	TILLOMED LABORATORIES LTD	XI
Pamidronate Disodium 9mg/ml Concentrate for Solution for Infusion	not available	PL 11311/0220	TILLOMED LABORATORIES LTD	XI
Pamisol 9 mg/ml, koncentrat do sporządzania roztworu do infuzji	SE/H/0420/003	11692	PFIZER EUROPE MA EEIG	PL
Pamisol 3 mg/ml, koncentrat do sporządzania roztworu do infuzji	SE/H/0420/001	11690	PFIZER EUROPE MA EEIG	PL
Pamisol 6 mg/ml, koncentrat do sporządzania roztworu do infuzji	SE/H/0420/002	11691	PFIZER EUROPE MA EEIG	PL
Pamidronaatdinatrium Hospira 3 mg/ml concentraat voor oplossing voor infusie	SE/H/0420/001	BE 237587	HOSPIRA BENELUX BVBA	BE
Pamidronaatdinatrium Hospira 3 mg/ml concentraat voor oplossing voor infusie	SE/H/0420/001	BE 237596	HOSPIRA BENELUX BVBA	BE
Pamidronaatdinatrium Hospira 6 mg/ml concentraat voor oplossing voor infusie	SE/H/0420/002	BE 237605	HOSPIRA BENELUX BVBA	BE
Pamidronaatdinatrium Hospira 9 mg/ml concentraat voor oplossing voor infusie	SE/H/0420/003	BE 237614	HOSPIRA BENELUX BVBA	BE
Pamidronatdinatrium "Pfizer", koncentrat til infusionsvæske, opløsning	SE/H/0420/001	33122	PFIZER APS	DK
Pamidronatdinatrium "Pfizer", koncentrat til infusionsvæske, opløsning	SE/H/0420/002	33123	PFIZER APS	DK
Pamidronatdinatrium "Pfizer", koncentrat til infusionsvæske, opløsning	SE/H/0420/003	33124	PFIZER APS	DK
Pamidronato Hospira 3 mg/ml Concentrado para solución para perfusión	SE/H/0420/001	64.945	PFIZER, S.L.	ES
Pamidronato Hospira 6 mg/ml Concentrado para solución para perfusión	SE/H/0420/002	64.946	PFIZER, S.L.	ES
Pamidronato Hospira 9 mg/ml Concentrado para solución para perfusión	SE/H/0420/003	64.947	PFIZER, S.L.	ES
Pamidronatdinatrium Pfizer 3 mg/ml koncentrat till infusionsvätska, lösning	SE/H/0420/001	17959	PFIZER AB	SE
Pamidronatdinatrium Pfizer 6 mg/ml	SE/H/0420/002	17960	PFIZER AB	SE

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koncentrat till infusionsvätska, lösning				
Pamidronatdinatrium Pfizer 9 mg/ml koncentrat till infusionsvätska, lösning	SE/H/0420/003	17961	PFIZER AB	SE
PAMIDRONATE DE SODIUM HOSPIRA 3 mg/ml, solution à diluer pour perfusion	SE/H/0420/001	34009 381 696 6 9	PFIZER HOLDING FRANCE	FR
PAMIDRONATE DE SODIUM HOSPIRA 3 mg/ml, solution à diluer pour perfusion	SE/H/0420/001	34009 381 697 2 0	PFIZER HOLDING FRANCE	FR
PAMIDRONATE DE SODIUM HOSPIRA 6 mg/ml, solution à diluer pour perfusion	SE/H/0420/002	34009 381 698 9 8	PFIZER HOLDING FRANCE	FR
PAMIDRONATE DE SODIUM HOSPIRA 9 mg/ml, solution à diluer pour perfusion	SE/H/0420/003	34009 381 699 5 9	PFIZER HOLDING FRANCE	FR
Pamidronat-Dinatrium Hospira 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0420/001	2009110025	HOSPIRA BENELUX BVBA	LU
Pamidronat-Dinatrium Hospira 6 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0420/002	2009110026	HOSPIRA BENELUX BVBA	LU
Pamidronat-Dinatrium Hospira 9 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0420/003	2009110027	HOSPIRA BENELUX BVBA	LU
Pamidronat Dinatrium Pfizer 6 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0420/002	1-25978	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Pamidronat Dinatrium Pfizer 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0420/001	1-25977	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Pamidronat Dinatrium Pfizer 9 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0420/003	1-25979	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Pamidronat Dinatrium Pfizer 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0420/001	1-25977	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Pamisol 3 mg/ml, koncentrat do sporządzania roztworu do infuzji	SE/H/0420/001	11690	PFIZER EUROPE MA EEIG	PL
Pamidronato Hospira 3 mg/ml Concentrado para solución para perfusión	SE/H/0420/001	64.945	PFIZER, S.L.	ES
Pamidronatdinatrium "Pfizer", koncentrat til	SE/H/0420/001	33122	PFIZER APS	DK

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infusionsvæske, opløsning				
Pamidran 3 mg/ml Concentrado para solução para perfusão	SE/H/0420/001	3967585	LABORATÓRIOS PFIZER, LDA.	PT
Pamidran 3 mg/ml Concentrado para solução para perfusão	SE/H/0420/001	3967486	LABORATÓRIOS PFIZER, LDA.	PT
Pamidran 6 mg/ml Concentrado para solução para perfusão	SE/H/0420/002	3967684	LABORATÓRIOS PFIZER, LDA.	PT
Pamidran 9 mg/ml Concentrado para solução para perfusão	SE/H/0420/003	3967783	LABORATÓRIOS PFIZER, LDA.	PT
Pamidronatdinatrium Pfizer 9 mg/ml, innrennslispykkni, lausn.	SE/H/0420/003	IS/1/05/008/03	PFIZER APS	IS
Pamidronatdinatrium Pfizer 6 mg/ml, innrennslispykkni, lausn.	SE/H/0420/002	IS/1/05/008/02	PFIZER APS	IS
Pamidronatdinatrium Pfizer 3 mg/ml, innrennslispykkni, lausn.	SE/H/0420/001	IS/1/05/008/01	PFIZER APS	IS
Pamidronatdinatrium Pfizer 3 mg/ml, innrennslispykkni, lausn.	SE/H/0420/001	IS/1/05/008/01	PFIZER APS	IS
Pamidronatdinatrium Pfizer 3 mg/ml konsentrat til infusionsvæske, oppløsning	SE/H/0420/001	01-11119	PFIZER AS	NO
Pamidronatdinatrium Pfizer 6 mg/ml konsentrat til infusionsvæske, oppløsning	SE/H/0420/002	01-11120	PFIZER AS	NO
Pamidronatdinatrium Pfizer 9 mg/ml konsentrat til infusionsvæske, oppløsning	SE/H/0420/003	01-11121	PFIZER AS	NO
Pamidronatdinatrium Pfizer 3 mg/ml konsentrat til infusionsvæske, oppløsning	SE/H/0420/001	01-11119	PFIZER AS	NO
Pamidronatdinatrium Pfizer 3 mg/ml konsentrat till infusionsvätska, lösning	SE/H/0420/001	17959	PFIZER AB	SE
Pamidronaatdinatrium Hospira 3mg/ml, concentraat voor oplossing voor infuus;	NL/H/0616/001	RVG 30872	HOSPIRA BENELUX BVBA	NL
Pamidronaatdinatrium Hospira 6mg/ml, concentraat voor oplossing voor infuus;	NL/H/0616/002	RVG 30873	HOSPIRA BENELUX BVBA	NL
Pamidronaatdinatrium Hospira 9mg/ml, concentraat voor oplossing voor infuus.	NL/H/0616/003	RVG 30874	HOSPIRA BENELUX BVBA	NL
Pamidronaatdinatrium Hospira 3mg/ml, concentraat voor oplossing voor infuus;	NL/H/0616/001	RVG 30872	HOSPIRA BENELUX BVBA	NL
Pamidronato Hikma 3 mg/ml Concentrado para solução para perfusão	not available	5052576	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT

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Pamidronato Hikma 6 mg/ml Concentrado para solução para perfusão	not available	5052600	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Pamidronato Hikma 9 mg/ml Concentrado para solução para perfusão	not available	5052618	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT