



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2024
EMA/490546/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): Zoledronic acid

Procedure No. PSUSA/00003149/202308



Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Zoledronsäure - 1 A Pharma 4 mg/100 ml Infusionslösung	DE/H/5089/001	84970.00.00	1 A PHARMA GMBH	DE
Zoledronic acid Ennogen 4 mg/5 ml concentrate for solution for infusion	not available	PL 40739/0233	ENNOGEN HEALTHCARE LIMITED	XI
Zoledronic acid Ennogen 4 mg/5 ml concentrate for solution for infusion	not available	PL 40739/0233	ENNOGEN HEALTHCARE LIMITED	XI
Zoledronsav Sandoz 4 mg/100 ml oldatos infúzió	AT/H/0411/002	OGYI-T-22283/10	SANDOZ HUNGÁRIA KFT	HU
ACIDE ZOLEDRONIQUE SANDOZ 4 mg/100 ml, solution pour perfusion	AT/H/0411/002	34009 586 953 0 8	SANDOZ	FR
Zoledronsäure Sandoz 4 mg/100 ml – Infusionslösung	AT/H/0411/002	1-31349	SANDOZ GMBH	AT
Zoledronsav Sandoz 4 mg/100 ml oldatos infúzió	AT/H/0411/002	OGYI-T-22283/04	SANDOZ HUNGÁRIA KFT	HU
Zoledronsav Sandoz 4 mg/100 ml oldatos infúzió	AT/H/0411/002	OGYI-T-22283/05	SANDOZ HUNGÁRIA KFT	HU
Zoledronsav Sandoz 4 mg/100 ml oldatos infúzió	AT/H/0411/002	OGYI-T-22283/06	SANDOZ HUNGÁRIA KFT	HU
Zoledronic acid Sandoz 4 mg/100 ml solution for infusion	AT/H/0411/002	PL 04416/1307	SANDOZ LTD	XI
Kyselina zoledrónová Sandoz 4 mg/100 ml infúzny roztok	AT/H/0411/002	87/0281/12-S	SANDOZ PHARMACEUTICALS D.D.	SK
ACIDE ZOLEDRONIQUE SANDOZ 4 mg/100 ml, solution pour perfusion	AT/H/0411/002	34009 224 088 9 7	SANDOZ	FR
ACIDE ZOLEDRONIQUE SANDOZ 4 mg/100 ml, solution pour perfusion	AT/H/0411/002	34009 582 943 0 3	SANDOZ	FR
ACIDE ZOLEDRONIQUE SANDOZ 4 mg/100 ml, solution pour perfusion	AT/H/0411/002	34009 582 944 7 1	SANDOZ	FR

Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Zoledronic acid Sandoz 4 mg/100 ml oplossing voor infusie	AT/H/0411/002	BE424715	SANDOZ N.V.	BE