



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 September 2025
EMADOC-1700519818-2419189
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): bendamustine hydrochloride

EURD list No. PSUSA/00003162/202501



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
Bendamustin Accord 25 mg/ml Konzentrat zur Herstellung einer Infusionslösung	AT/H/0497/002	141152	ACCORD HEALTHCARE B.V.	AT
Bendamustin Accord 25 mg/ml Konzentrat zur Herstellung einer Infusionslösung	AT/H/0497/002	141152	ACCORD HEALTHCARE B.V.	AT
Bendamustin Accord 25 mg/ml Konzentrat zur Herstellung einer Infusionslösung	AT/H/0497/002	141152	ACCORD HEALTHCARE B.V.	AT
Levact 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung einer Infusionslösung	DE/H/1250/001	1-29469	PHARMAAND GMBH	AT
Levact 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung einer Infusionslösung	DE/H/1250/001	1-29469	PHARMAAND GMBH	AT
Bendamustine Accord 25 mg/ml concentraat voor oplossing voor infusie	AT/H/0497/002	BE662135	ACCORD HEALTHCARE B.V.	BE
Bendamustine Accord 25 mg/ml concentraat voor oplossing voor infusie	AT/H/0497/002	BE597093	ACCORD HEALTHCARE B.V.	BE
Bendamustine Accord 25 mg/ml solution à diluer pour perfusion	AT/H/0497/002	BE662135	ACCORD HEALTHCARE B.V.	BE
Bendamustine Accord 25 mg/ml solution à diluer pour perfusion	AT/H/0497/002	BE597093	ACCORD HEALTHCARE B.V.	BE
Levact 2,5 mg/ml poudre pour solution à diluer pour perfusion	DE/H/1250/001	BE376013	PHARMAAND GMBH	BE
Levact 2,5 mg/ml poudre pour solution à diluer pour perfusion	DE/H/1250/001	BE376022	PHARMAAND GMBH	BE
Levact 2,5 mg/ml, poeder voor concentraat voor oplossing voor infusie	DE/H/1250/001	BE376022	PHARMAAND GMBH	BE
Levact 2,5 mg/ml, poeder voor concentraat voor oplossing	DE/H/1250/001	BE376013	PHARMAAND GMBH	BE

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voor infusie				
Бендамустин Акорд 25 mg/ml концентрат за инфузионен разтвор	AT/H/0497/002	20220124	ACCORD HEALTHCARE POLSKA SP. Z O.O.	BG
Левакт 2,5 mg/ml прах за концентрат за инфузионен разтвор	DE/H/1250/001	20110498	PHARMAAND GMBH	BG
Левакт 2,5 mg/ml прах за концентрат за инфузионен разтвор	DE/H/1250/001	20110498	PHARMAAND GMBH	BG
Bendamustine Accord 25 mg/ml πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	AT/H/0497/002	023634	ACCORD HEALTHCARE S.L.U.	CY
Bendamustine Accord 25 mg/ml koncentrát pro infuzní roztok	AT/H/0497/002	44/102/20-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
Bendamustine Accord 25 mg/ml koncentrát pro infuzní roztok	AT/H/0497/002	44/102/20-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
Bendamustin Accord 25 mg/ml Konzentrat zur Herstellung einer Infusionslösung	AT/H/0497/002	7000246.00.00	ACCORD HEALTHCARE B.V.	DE
Bendamustin AqVida 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/8077/001/DC	2201397.00.00	AQVIDA GMBH	DE
Bendamustin AqVida 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	7016822.00.00	AQVIDA GMBH	DE
Bendamustin AqVida 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	7016822.00.00	AQVIDA GMBH	DE
Bendamustin AqVida 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	7016822.00.00	AQVIDA GMBH	DE

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Herstellung einer Infusionslösung				
Bendamustin AqVida 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	7016822.00.00	AQVIDA GMBH	DE
Bendamustin AqVida 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	7016822.00.00	AQVIDA GMBH	DE
Bendamustin AqVida 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	7016822.00.00	AQVIDA GMBH	DE
Bendamustin beta 180 mg/4 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4539/001	95550.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Benda-onkovis 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	N.A.	7016823.00.00	ONKOVIS GMBH	DE
Benda-onkovis 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	N.A.	7016823.00.00	ONKOVIS GMBH	DE
Benda-onkovis 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	N.A.	7016823.00.00	ONKOVIS GMBH	DE
Benda-onkovis 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	N.A.	7016823.00.00	ONKOVIS GMBH	DE
Benda-onkovis 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	N.A.	7016823.00.00	ONKOVIS GMBH	DE
Benda-onkovis 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	N.A.	7016823.00.00	ONKOVIS GMBH	DE
Levact 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung	DE/H/1250/001	70972.00.00	PHARMAAND GMBH	DE

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einer Infusionslösung				
Levact 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung einer Infusionslösung	DE/H/1250/001	70972.00.00	PHARMAAND GMBH	DE
Bendamustinhydrochlorid "Accord", konzentrat til infusionsvæske, opløsning	AT/H/0497/002	64275	ACCORD HEALTHCARE B.V.	DK
Bendamustine Accord 25 mg/ml infusioonilahuse kontsentraat	AT/H/0497/002	1054622	ACCORD HEALTHCARE B.V.	EE
Bendamustine Accord 25 mg/ml infusioonilahuse kontsentraat	AT/H/0497/002	1054622	ACCORD HEALTHCARE B.V.	EE
Bendamustina Accord 25 mg/ml concentrado para solución para perfusión	AT/H/0497/002	86779	ACCORD HEALTHCARE S.L.U.	ES
Bendamustina Dr. Reddys 45 mg/ml concentrado para solución para perfusión	DE/H/4539/001	82784	REDDY PHARMA IBERIA, S.A.	ES
Levact 2,5 mg/ml, polvo para concentrado para solución para perfusión.	DE/H/1250/001	72571	PHARMAAND GMBH	ES
Levact 2,5 mg/ml, polvo para concentrado para solución para perfusión.	DE/H/1250/001	72571	PHARMAAND GMBH	ES
Bendamustine Accord 25 mg/ml infuusiokonsentraatti, liuosta varten	AT/H/0497/002	37963	ACCORD HEALTHCARE B.V.	FI
Bendamustine Accord 25 mg/ml infuusiokonsentraatti, liuosta varten	AT/H/0497/002	37963	ACCORD HEALTHCARE B.V.	FI
BENDAMUSTINE ACCORD 25 mg/mL, solution à diluer pour perfusion	AT/H/0497/002	34009 550 986 0 7	ACCORD HEALTHCARE FRANCE SAS	FR
BENDAMUSTINE ACCORD 25 mg/mL, solution à diluer pour perfusion	AT/H/0497/002	34009 550 986 1 4	ACCORD HEALTHCARE FRANCE SAS	FR

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BENDAMUSTINE ACCORD 25 mg/mL, solution à diluer pour perfusion	AT/H/0497/002	34009 550 880 6 6	ACCORD HEALTHCARE FRANCE SAS	FR
BENDAMUSTINE ACCORD 25 mg/mL, solution à diluer pour perfusion	AT/H/0497/002	34009 550 880 7 3	ACCORD HEALTHCARE FRANCE SAS	FR
BENDAMUSTINE REDDY PHARMA 180 mg/4 ml, solution concentrée à diluer pour solution pour perfusion	DE/H/4539/001	34009 550 422 8 0	REDDY PHARMA SAS	FR
BENDAMUSTINE REDDY PHARMA 180 mg/4 ml, solution concentrée à diluer pour solution pour perfusion	DE/H/4539/001	34009 550 422 9 7	REDDY PHARMA SAS	FR
Bendamustine Accord 25 mg / ml πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	AT/H/0497/002	4807/18-01-2023	ACCORD HEALTHCARE S.L.U.	GR
Bendamustine Accord 25 mg / ml πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	AT/H/0497/002	4807/18-01-2023	ACCORD HEALTHCARE S.L.U.	GR
Bendamustine Accord 25 mg/ml koncentrátum oldatos infúzióhoz	AT/H/0497/002	OGYI-T-22964/09	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Bendamustine Accord 25 mg/ml koncentrátum oldatos infúzióhoz	AT/H/0497/002	OGYI-T-22964/08	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Bendamustine 25 mg/ml concentrate for solution for infusion	AT/H/0497/002	PA2315/077/003	ACCORD HEALTHCARE IRELAND LIMITED	IE
Bendamustine Accord 25 mg/ml innrennsliþykkni, lausn	AT/H/0497/002	IS/1/22/023/01	ACCORD HEALTHCARE B.V.	IS
Bendamustine Accord 25 mg/ml innrennsliþykkni, lausn	AT/H/0497/002	IS/1/22/023/01	ACCORD HEALTHCARE B.V.	IS
Bendamustina Accord 25 mg/ml concentrato per	AT/H/0497/002	044327082	ACCORD HEALTHCARE S.L.U.	IT

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soluzione per infusione				
Bendamustina Accord 25 mg/ml concentrato per soluzione per infusione	AT/H/0497/002	044327068	ACCORD HEALTHCARE S.L.U.	IT
Bendamustina Accord 25 mg/ml concentrato per soluzione per infusione	AT/H/0497/002	044327070	ACCORD HEALTHCARE S.L.U.	IT
Levact 2,5 mg/ml polvere per concentrato per soluzione per infusione	DE/H/1250/001	040175010	PHARMAAND GMBH	IT
Levact 2,5 mg/ml polvere per concentrato per soluzione per infusione	DE/H/1250/001	040175022 - 10 FLAONCINI IN VETRO DA 25 MG	PHARMAAND GMBH	IT
Levact 2,5 mg/ml polvere per concentrato per soluzione per infusione	DE/H/1250/001	040175034 - 20 FLAONCINI IN VETRO DA 25 MG	PHARMAAND GMBH	IT
Levact 2,5 mg/ml polvere per concentrato per soluzione per infusione	DE/H/1250/001	040175046 - 5 FLAONCINI IN VETRO DA 100 MG	PHARMAAND GMBH	IT
STINRED 180 mg/4 ml concentrato per soluzione per infusione	DE/H/4539/001	044583019	DR. REDDY'S S.R.L.	IT
STINRED 180 mg/4 ml concentrato per soluzione per infusione	DE/H/4539/001	044583021	DR. REDDY'S S.R.L.	IT
Bendamustine Accord 25 mg/ml koncentratas infuziniam tirpalui	AT/H/0497/002	LT/1/22/4943/003	ACCORD HEALTHCARE B.V.	LT
Bendamustine Accord 25 mg/ml koncentratas infuziniam tirpalui	AT/H/0497/002	LT/1/22/4943/004	ACCORD HEALTHCARE B.V.	LT
Bendamustine Accord 25 mg/ml koncentratas infuziniam tirpalui	AT/H/0497/002	LT/1/22/4943/001	ACCORD HEALTHCARE B.V.	LT
Bendamustine Accord 25 mg/ml koncentratas infuziniam tirpalui	AT/H/0497/002	LT/1/22/4943/002	ACCORD HEALTHCARE B.V.	LT

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Levact 2,5 mg/ml poudre pour solution à diluer pour perfusion	DE/H/1250/001	1665/11010151	PHARMAAND GMBH	LU
Levact 2,5 mg/ml poudre pour solution à diluer pour perfusion	DE/H/1250/001	1665/11010151	PHARMAAND GMBH	LU
Bendamustine Accord 25 mg/ml koncentrāts infūziju šķīduma pagatavošanai	AT/H/0497/002	22-0036	ACCORD HEALTHCARE B.V.	LV
Bendamustine Accord 25 mg/ml koncentrāts infūziju šķīduma pagatavošanai	AT/H/0497/002	22-0036	ACCORD HEALTHCARE B.V.	LV
Bendamustine Accord 25 mg/ml concentraat voor oplossing voor infusie	AT/H/0497/002	RVG 126621	ACCORD HEALTHCARE B.V.	NL
Bendamustine Accord 25 mg/ml concentraat voor oplossing voor infusie	AT/H/0497/002	RVG 126621	ACCORD HEALTHCARE B.V.	NL
Levact 2,5 mg/ml, poeder voor concentraat voor oplossing voor infusie	DE/H/1250/001	RVG 109342	PHARMAAND GMBH	NL
Levact 2,5 mg/ml, poeder voor concentraat voor oplossing voor infusie	DE/H/1250/001	RVG 109342	PHARMAAND GMBH	NL
Bendamustine Accord 25 mg/ml konsentrat til infusjonsvæske, oppløsning	AT/H/0497/002	20-13408	ACCORD HEALTHCARE B.V.	NO
Bendamustine Accord 25 mg/ml konsentrat til infusjonsvæske, oppløsning	AT/H/0497/002	20-13408	ACCORD HEALTHCARE B.V.	NO
Bendamustine Accord, 25 mg/ml, koncentrat do sporządzania roztworu do infuzji	AT/H/0497/002	27384	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
Bendamustina Accord 25 mg/ml concentrado para solução para perfusão	AT/H/0497/002	5879655	ACCORD HEALTHCARE S.L.U.	PT
Bendamustina Accord 25 mg/ml concentrado para	AT/H/0497/002	5834403	ACCORD HEALTHCARE S.L.U.	PT

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solução para perfusão				
Levact 2,5 mg/ml pó para concentrado para solução para perfusão	DE/H/1250/001	5411277	PHARMAAND GMBH	PT
Levact 2,5 mg/ml pó para concentrado para solução para perfusão	DE/H/1250/001	5411269	PHARMAAND GMBH	PT
Bendamustina Accord 25 mg/ml concentrat pentru solutie perfuzabila	AT/H/0497/002	14484/2022/01	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Bendamustina Accord 25 mg/ml concentrat pentru solutie perfuzabila	AT/H/0497/002	14484/2022/02	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Bendamustine Accord 25 mg/ml koncentrat till infusionsvätska, lösning	AT/H/0497/002	60583	ACCORD HEALTHCARE B.V.	SE
Bendamustin Accord 25 mg/ml koncentrat za raztopino za infundiranje	AT/H/0497/002	H/16/02194/008	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Bendamustin Accord 25 mg/ml koncentrat za raztopino za infundiranje	AT/H/0497/002	H/16/02194/009	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Bendamustin Accord 25 mg/ml koncentrat za raztopino za infundiranje	AT/H/0497/002	H/16/02194/006	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Bendamustin Accord 25 mg/ml koncentrat za raztopino za infundiranje	AT/H/0497/002	H/16/02194/007	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Bendamustine Accord 25 mg/ml koncentrát na infúzny roztok	AT/H/0497/002	44/0259/23-S	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SK
Bendamustine Accord 25 mg/ml koncentrát na infúzny roztok	AT/H/0497/002	44/0259/23-S	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SK
Levact 2,5 mg/ml, prášok na infúzny koncentrát	DE/H/1250/001	44/0439/11-S	PHARMAAND GMBH	SK
Levact 2,5 mg/ml, prášok na	DE/H/1250/001	44/0439/11-S	PHARMAAND GMBH	SK

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infúzny koncentrát				
Bendamustine hydrochloride 180 mg/4 ml Concentrate For Solution For Infusion	DE/H/4539/001	PL 08553/0571	DR. REDDY'S LABORATORIES (UK) LTD	XI
Bendamustine hydrochloride 25 mg/ml concentrate for solution for infusion	not available	PL 20075/1397	ACCORD HEALTHCARE LIMITED	XI
Bendamustine hydrochloride 25 mg/ml concentrate for solution for infusion	not available	PL 20075/1397	ACCORD HEALTHCARE LIMITED	XI