



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2022
EMA/37632/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: vinorelbine

Procedure no.: PSUSA/00003124/202204

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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
NAVELBINE 20 mg Weichkapseln	not available	50133.00.00	PIERRE FABRE PHARMA GMBH	DE
NAVELBINE 30 mg Weichkapseln	not available	50133.01.00	PIERRE FABRE PHARMA GMBH	DE
NAVELBINE 80 mg Weichkapseln	not available	50133.03.00	PIERRE FABRE PHARMA GMBH	DE
NAVELBINE 20 mg Weichkapseln	not available	50133.00.00	PIERRE FABRE PHARMA GMBH	DE
NAVELBINE 30 mg Weichkapseln	not available	50133.01.00	PIERRE FABRE PHARMA GMBH	DE
NAVELBINE 20 mg μαλακό καψάκιο	not available	41579/23-9-2008	PIERRE FABRE FARMAKA SA	GR
NAVELBINE 30 mg μαλακό καψάκιο	not available	41580/23-9-2008	PIERRE FABRE FARMAKA SA	GR
Navelbine® 20 mg - Kapseln	not available	1-24690	PIERRE FABRE MEDICAMENT	AT
Navelbine® 30 mg - Kapseln	not available	1-24691	PIERRE FABRE MEDICAMENT	AT
Navelbine® 80 mg - Kapseln	not available	1-24693	PIERRE FABRE MEDICAMENT	AT
Navelbine® 20 mg - Kapseln	not available	1-24690	PIERRE FABRE MEDICAMENT	AT
Navelbine® 20 mg - Kapseln	not available	1-24690	PIERRE FABRE MEDICAMENT	AT
Navelbine® 20 mg - Kapseln	not available	1-24690	PIERRE FABRE MEDICAMENT	AT
Navelbine® 30 mg - Kapseln	not available	1-24691	PIERRE FABRE MEDICAMENT	AT
Navelbine® 30 mg - Kapseln	not available	1-24691	PIERRE FABRE MEDICAMENT	AT
Navelbine® 30 mg - Kapseln	not available	1-24691	PIERRE FABRE MEDICAMENT	AT
Navelbine 10 mg/ml infuusiokonsentraatti, liuosta varten	not available	12191	PIERRE FABRE PHARMA NORDEN AB	FI

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Navelbine 10 mg/ml infuusiokonsentraatti, liuosta varten	not available	12191	PIERRE FABRE PHARMA NORDEN AB	FI
Navelbine 10 mg/ml infuusiokonsentraatti, liuosta varten	not available	12191	PIERRE FABRE PHARMA NORDEN AB	FI
Navelbine 10 mg/ml infuusiokonsentraatti, liuosta varten	not available	12191	PIERRE FABRE PHARMA NORDEN AB	FI
Navelbine 10 mg/ml infuusiokonsentraatti, liuosta varten	not available	12191	PIERRE FABRE PHARMA NORDEN AB	FI
Navelbine 10 mg/ml infuusiokonsentraatti, liuosta varten	not available	12191	PIERRE FABRE PHARMA NORDEN AB	FI
Navelbine® 10 mg - Infusionskonzentrat	not available	1-20425	PIERRE FABRE MEDICAMENT	AT
Navelbine® 50 mg - Infusionskonzentrat	not available	1-20428	PIERRE FABRE MEDICAMENT	AT
NAVELBINE 10 mg/1 ml koncentrát pro infuzní roztok	not available	44/136/92-S/C	PIERRE FABRE MEDICAMENT	CZ
NAVELBINE 10 mg/1 ml koncentrát pro infuzní roztok	not available	44/136/92-S/C	PIERRE FABRE MEDICAMENT	CZ
NAVELBINE 10 mg/1 ml koncentrát pro infuzní roztok	not available	44/136/92-S/C	PIERRE FABRE MEDICAMENT	CZ
NAVELBINE 10 mg/1 ml koncentrát pro infuzní roztok	not available	44/136/92-S/C	PIERRE FABRE MEDICAMENT	CZ
Navelbine 20 mg lágy kapszula	not available	OGYI-T-472 1/03	PIERRE FABRE MEDICAMENT	HU
Navelbine 30 mg lágy kapszula	not available	OGYI-T-4721/04	PIERRE FABRE MEDICAMENT	HU

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
Navelbine 20 mg kapsel, myk	not available	02/1154	PIERRE FABRE PHARMA NORDEN AB	NO
Navelbine 80 mg kapsel, myk	not available	02/1157	PIERRE FABRE PHARMA NORDEN AB	NO
Navelbine 30 mg kapsel, myk	not available	02/1155	PIERRE FABRE PHARMA NORDEN AB	NO
NAVELBINE 20 mg capsules molles	not available	BE276735	PIERRE FABRE MEDICAMENT	BE
NAVELBINE 30 mg capsules molles	not available	BE276744	PIERRE FABRE MEDICAMENT	BE
NAVELBINE 30 mg capsules, zacht	not available	BE276744	PIERRE FABRE MEDICAMENT	BE
NAVELBINE 20 mg capsules, zacht	not available	BE276735	PIERRE FABRE MEDICAMENT	BE
NAVELBINE ® 20 mg kapseli, pehmeä	not available	15882	PIERRE FABRE PHARMA NORDEN AB	FI
NAVELBINE ® 30 mg kapseli, pehmeä	not available	15883	PIERRE FABRE PHARMA NORDEN AB	FI
NAVELBINE ® 80 mg kapseli, pehmeä	not available	15885	PIERRE FABRE PHARMA NORDEN AB	FI
NAVELBINE, 20 mg, kapsułki miękkie	not available	9450	PIERRE FABRE MEDICAMENT	PL
NAVELBINE, 30 mg, kapsułki miękkie	not available	9451	PIERRE FABRE MEDICAMENT	PL
Navelbine, koncentrat til infusionsvæske, opløsning	not available	16662	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine, koncentrat til infusionsvæske, opløsning	not available	16662	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine, koncentrat til infusionsvæske, opløsning	not available	16662	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine, koncentrat til infusionsvæske, opløsning	not available	16662	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine, koncentrat til infusionsvæske, opløsning	not available	16662	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine, koncentrat til	not available	16662	PIERRE FABRE PHARMA	DK

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infusionsvæske, opløsning			NORDEN AB	
NAVELBINE 50 mg/5 ml, solution injectable en flacon	not available	34009 331 845 8 2	PIERRE FABRE MEDICAMENT	FR
NAVELBINE 10 mg/1 ml, solution injectable en flacon	not available	34009 331 903 8 5	PIERRE FABRE MEDICAMENT	FR
NAVELBINE 10 mg/1 ml, solution injectable en flacon	not available	34009 331 904 4 6	PIERRE FABRE MEDICAMENT	FR
NAVELBINE 50 mg/5 ml, solution injectable en flacon	not available	34009 331 844 1 4	PIERRE FABRE MEDICAMENT	FR
NAVELBINE 20 mg cápsulas blandas	not available	65.978	PIERRE FABRE IBERICA, S.A.	ES
NAVELBINE 30 mg cápsulas blandas	not available	65.979	PIERRE FABRE IBERICA, S.A.	ES
NAVELBINE 30 mg capsules, zacht	not available	RVG 111394	PIERRE FABRE MEDICAMENT	NL
NAVELBINE 20 mg capsules, zacht	not available	RVG 111393	PIERRE FABRE MEDICAMENT	NL
NAVELBINE® 10 mg / ml concentrate for solution for infusion	not available	PA 0327/011/001	PIERRE FABRE MEDICAMENT	IE
NAVELBINE® 10 mg / ml concentrate for solution for infusion	not available	PA 0327/011/001	PIERRE FABRE MEDICAMENT	IE
NAVELBINE® 10 mg / ml concentrate for solution for infusion	not available	PA 0327/011/001	PIERRE FABRE MEDICAMENT	IE
NAVELBINE 10 mg / 1 ml Konzentrat zur Herstellung einer Infusionslösung	not available	33071.00.00	PIERRE FABRE PHARMA GMBH	DE
NAVELBINE 50 mg / 5 ml Konzentrat zur Herstellung	not available	33071.02.00	PIERRE FABRE PHARMA GMBH	DE

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einer Infusionslösung				
NAVELBINE 10 mg / 1 ml Konzentrat zur Herstellung einer Infusionslösung	not available	33071.00.00	PIERRE FABRE PHARMA GMBH	DE
NAVELBINE 50 mg / 5 ml Konzentrat zur Herstellung einer Infusionslösung	not available	33071.02.00	PIERRE FABRE PHARMA GMBH	DE
Navelbine 50 mg/5 ml solution à diluer pour perfusion	not available	BE177581	PIERRE FABRE MEDICAMENT	BE
Navelbine 50 mg/5 ml concentraat voor oplossing voor intraveneuze infusie	not available	BE177581	PIERRE FABRE MEDICAMENT	BE
Navelbine 40 mg/4 ml solution à diluer pour perfusion	not available	BE177597	PIERRE FABRE MEDICAMENT	BE
Navelbine 10 mg/1 ml solution à diluer pour perfusion	not available	BE177606	PIERRE FABRE MEDICAMENT	BE
Navelbine 40 mg/4 ml concentraat voor oplossing voor intraveneuze infusie	not available	BE177597	PIERRE FABRE MEDICAMENT	BE
Navelbine 10 mg/1 ml concentraat voor oplossing voor intraveneuze infusie	not available	BE177606	PIERRE FABRE MEDICAMENT	BE
Navelbine 50 mg/5 ml solution à diluer pour perfusion	not available	BE177581	PIERRE FABRE MEDICAMENT	BE
Navelbine 40 mg/4 ml solution à diluer pour perfusion	not available	BE177597	PIERRE FABRE MEDICAMENT	BE
Navelbine 10 mg/1 ml solution à diluer pour perfusion	not available	BE177606	PIERRE FABRE MEDICAMENT	BE
Navelbine 50 mg/5 ml	not available	BE177581	PIERRE FABRE MEDICAMENT	BE

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concentraat voor oplossing voor intraveneuze infusie				
Navelbine 40 mg/4 ml concentraat voor oplossing voor intraveneuze infusie	not available	BE177597	PIERRE FABRE MEDICAMENT	BE
Navelbine 10 mg/1 ml concentraat voor oplossing voor intraveneuze infusie	not available	BE177606	PIERRE FABRE MEDICAMENT	BE
NAVELBINE 10 mg/ml koncentrāts infūziju šķīduma pagatavošanai	not available	99-0347	PIERRE FABRE MEDICAMENT	LV
NAVELBINE 10 mg/ml koncentrāts infūziju šķīduma pagatavošanai	not available	99-0347	PIERRE FABRE MEDICAMENT	LV
NAVELBINE 10 mg/ml koncentrāts infūziju šķīduma pagatavošanai	not available	99-0347	PIERRE FABRE MEDICAMENT	LV
NAVELBINE 10 mg/ml koncentrāts infūziju šķīduma pagatavošanai	not available	99-0347	PIERRE FABRE MEDICAMENT	LV
NAVELBINE, 10 mg/ml, koncentrat do sporządzania roztworu do infuzji	not available	R/1736	PIERRE FABRE MEDICAMENT	PL
NAVELBINE, 10 mg/ml, koncentrat do sporządzania roztworu do infuzji	not available	R/1736	PIERRE FABRE MEDICAMENT	PL
NAVELBINE 10 mg/ml concentrado para solución para perfusión	not available	59.300	PIERRE FABRE IBERICA, S.A.	ES
NAVELBINE 10 mg/ml concentrado para solución para perfusión	not available	59.300	PIERRE FABRE IBERICA, S.A.	ES
Navelbine 10mg/ml, concentrate for solution for infusion	not available	017884	PIERRE FABRE MEDICAMENT	CY

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
NAVELBINE® 20 mg soft capsule	not available	PA 0329/011/001	PIERRE FABRE MEDICAMENT	IE
NAVELBINE® 30 mg soft capsule	not available	PA 0329/011/002	PIERRE FABRE MEDICAMENT	IE
NAVELBINE® 80 mg soft capsule	not available	PA 0329/011/004	PIERRE FABRE MEDICAMENT	IE
NAVELBINE 20 mg, capsule molle	not available	0311211	PIERRE FABRE MEDICAMENT	LU
NAVELBINE 30 mg, capsule molle	not available	0724/01/12/0035	PIERRE FABRE MEDICAMENT	LU
NAVELBINE 20 mg capsule moi	not available	12681/2019/01	PIERRE FABRE MEDICAMENT	RO
NAVELBINE 30 mg capsule moi	not available	12682/2019/01	PIERRE FABRE MEDICAMENT	RO
NAVELBINE 30 mg capsule moi	not available	12682/2019/02	PIERRE FABRE MEDICAMENT	RO
NAVELBINE 20 mg capsule moi	not available	12681/2019/02	PIERRE FABRE MEDICAMENT	RO
NAVELBINE 50 mg/5 ml, solution injectable en flacon	not available	0195951	PIERRE FABRE MEDICAMENT	LU
NAVELBINE 10 mg/1 ml, solution injectable en flacon	not available	0193988	PIERRE FABRE MEDICAMENT	LU
NAVELBINE 50 mg/5 ml, solution injectable en flacon	not available	0196641	PIERRE FABRE MEDICAMENT	LU
NAVELBINE 10 mg/1 ml, solution injectable en flacon	not available	0193974	PIERRE FABRE MEDICAMENT	LU
NAVELBINE 30 mg pehmekapsel	not available	854814	PIERRE FABRE MEDICAMENT	EE
NAVELBINE 20 mg, capsule molle	not available	34009 365 948 4 5	PIERRE FABRE MEDICAMENT	FR
NAVELBINE 30 mg, capsule	not available	34009 365 949 0 6	PIERRE FABRE MEDICAMENT	FR

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molle				
Navelbine 30 mg mjúk hylki	not available	IS/1/03/135/02	PIERRE FABRE PHARMA NORDEN AB	IS
Navelbine 80 mg mjúk hylki	not available	IS/1/03/135/04	PIERRE FABRE PHARMA NORDEN AB	IS
Navelbine 20 mg mjúk hylki	not available	IS/1/03/135/01	PIERRE FABRE PHARMA NORDEN AB	IS
NAVELBINE 10 mg/ml, concentraat voor oplossing voor infusie	not available	RVG 18020	PIERRE FABRE MEDICAMENT	NL
NAVELBINE 10 mg/ml, concentraat voor oplossing voor infusie	not available	RVG 18020	PIERRE FABRE MEDICAMENT	NL
NAVELBINE 10 mg/ml, concentraat voor oplossing voor infusie	not available	RVG 18020	PIERRE FABRE MEDICAMENT	NL
NAVELBINE 10 mg/ml concentrato per soluzione per infusione	not available	027865082	PIERRE FABRE PHARMA S.R.L.	IT
NAVELBINE 10 mg/ml concentrato per soluzione per infusione	not available	027865094	PIERRE FABRE PHARMA S.R.L.	IT
NAVELBINE ORAL 20 mg měkké tobolky	not available	44/238/02-C	PIERRE FABRE MEDICAMENT	CZ
NAVELBINE ORAL 30 mg měkké tobolky	not available	44/239/02-C	PIERRE FABRE MEDICAMENT	CZ
Navelbine 10 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-4721/01	PIERRE FABRE MEDICAMENT	HU
Navelbine 10 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-4721/02	PIERRE FABRE MEDICAMENT	HU
NAVELBINE 20 mg capsule molli	not available	027865106	PIERRE FABRE PHARMA S.R.L.	IT
NAVELBINE 30 mg capsule	not available	027865118	PIERRE FABRE PHARMA S.R.L.	IT

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molli				
NAVELBINE 20 mg minkštosios kapsulės	not available	LT/1/97/2874/005	PIERRE FABRE MEDICAMENT	LT
NAVELBINE 30 mg minkštosios kapsulės	not available	LT/1/97/2874/006	PIERRE FABRE MEDICAMENT	LT
NAVELBINE ORAL 20 mg mäkké kapsuly	not available	44/0131/02-S	PIERRE FABRE MEDICAMENT	SK
NAVELBINE ORAL 30 mg mäkké kapsuly	not available	44/0132/02-S	PIERRE FABRE MEDICAMENT	SK
NAVELBINE 10 mg koncentrát na infúzny roztok	not available	44/0136/92-S	PIERRE FABRE MEDICAMENT	SK
NAVELBINE 10 mg koncentrát na infúzny roztok	not available	44/0136/92-S	PIERRE FABRE MEDICAMENT	SK
NAVELBINE 10 mg koncentrát na infúzny roztok	not available	44/0136/92-S	PIERRE FABRE MEDICAMENT	SK
NAVELBINE 10 mg koncentrát na infúzny roztok	not available	44/0136/92-S	PIERRE FABRE MEDICAMENT	SK
Navelbine 30 mg mjúk hylki	not available	IS/1/03/135/02	PIERRE FABRE PHARMA NORDEN AB	IS
Navelbine 80 mg mjúk hylki	not available	IS/1/03/135/04	PIERRE FABRE PHARMA NORDEN AB	IS
Navelbine 20 mg mjúk hylki	not available	IS/1/03/135/01	PIERRE FABRE PHARMA NORDEN AB	IS
NAVELBINE 20 mg cápsula mole	not available	3528288	PIERRE FABRE MÉDICAMENT PORTUGAL, LDA.	PT
NAVELBINE 30 mg cápsula mole	not available	3528387	PIERRE FABRE MÉDICAMENT PORTUGAL, LDA.	PT
Navelbine 20 mg mjuk kapsel	not available	16379	PIERRE FABRE PHARMA NORDEN AB	SE
Navelbine 30 mg mjuk kapsel	not available	16380	PIERRE FABRE PHARMA NORDEN AB	SE

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Navelbine 80 mg mjuk kapsel	not available	16382	PIERRE FABRE PHARMA NORDEN AB	SE
Navelbine, bløde kapsler	not available	33326	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine, bløde kapsler	not available	33327	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine, bløde kapsler	not available	33329	PIERRE FABRE PHARMA NORDEN AB	DK