



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2017
EMA/795271/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: vinorelbine

Procedure no.: PSUSA/00003124/201704



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 50 mg/5 ml solution à diluer pour perfusion	not available	BE177581	SAS PIERRE FABRE MEDICAMENT	BE
Navelbine, koncentrat til infusionsvæske, opløsning	not available	16662	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine 10 mg/ml, ενέσιμο διάλυμα	not available	41571/23-9-2008	PIERRE FABRE FARMAKA SA	GR
Navelbine 10 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-4721/01	SAS PIERRE FABRE MEDICAMENT	HU
NAVELBINE 10 mg/ml concentrato per soluzione per infusione	not available	027865082	PIERRE FABRE PHARMA S.R.L.	IT
NAVELBINE 10 mg/ml koncentrāts infūziju šķīduma pagatavošanai	not available	99-0347	PIERRE FABRE MEDICAMENT	LV
Navelbine 10 mg/ml koncentrat till infusionsvätska, lösning	not available	12784	PIERRE FABRE PHARMA NORDEN AB/SW	SE
NAVELBINE 20 mg capsules molles	not available	BE276735	PIERRE FABRE MEDICAMENT	BE
Navelbine, bløde kapsler	not available	33326	PIERRE FABRE PHARMA NORDEN AB	DK
NAVELBINE 20 mg μαλακό καψάκιο	not available	41579	PIERRE FABRE FARMAKA / GREECE	GR
NAVELBINE 20 mg capsule molli	not available	027865106	PIERRE FABRE PHARMA S.R.L.	IT
NAVELBINE 20 mg, capsule molle	not available	0724/01/12/0034	PIERRE FABRE MEDICAMENT	LU
Navelbine, kapsułka miękka, 20 mg	not available	9450	SAS PIERRE FABRE MEDICAMENT	PL
NAVELBINE 20 mg, cápsula mole	not available	3528288	PFM / PORTUGAL	PT
NAVELBINE 20 mg capsule moi	not available	6075/2005/01	PIERRE FABRE MEDICAMENT	RO

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 mjuk kapsel	not available	16379	PIERRE FABRE PHARMA NORDEN AB/SW	SE
NAVELBINE 30 mg capsules molles	not available	BE276744	PIERRE FABRE MEDICAMENT	BE
Navelbine, bløde kapsler	not available	33327	PIERRE FABRE PHARMA NORDEN AB	DK
NAVELBINE 30 mg μαλακό καψάκιο	not available	41580/23-9-2008	PIERRE FABRE FARMAKA / GREECE	GR
NAVELBINE 30 mg capsule molli	not available	027865118	PFM PHARMA / ITALY	IT
NAVELBINE 30 mg, capsule molle	not available	0724/01/12/0035	PIERRE FABRE MEDICAMENT	LU
Navelbine, kapsułka miękka, 30 mg	not available	9451	SAS PIERRE FABRE MEDICAMENT	PL
NAVELBINE 30 mg, cápsula mole	not available	3528387	PFM / PORTUGAL	PT
NAVELBINE 30 mg capsule moi	not available	6076/2005/01	SAS PIERRE FABRE MEDICAMENT	RO
Navelbine 30 mg mjuk kapsel	not available	16380	PIERRE FABRE PHARMA NORDEN AB/SW	SE
Navelbine, bløde kapsler	not available	33329	PIERRE FABRE PHARMA NORDEN AB	DK
Navelbine 80 mg mjuk kapsel	not available	16382	PIERRE FABRE PHARMA NORDEN AB/SW	SE
Navelbine20 mg kapsel, myk	not available	02/1154	PIERRE FABRE PHARMA NORDEN AB	NO
Navelbine80 mg kapsel, myk	not available	02/1157	PIERRE FABRE PHARMA NORDEN AB	NO
Navelbine30 mg kapsel, myk	not available	02/1155	PIERRE FABRE PHARMA NORDEN AB	NO

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 10 mg/ml, konsentrat til infusjonsvæske	not available	95-2385	PIERRE FABRE PHARMA NORDEN AB	NO
Navelbine 50 mg/5 ml concentraat voor oplossing voor intraveneuze infusie	not available	BE177581	SAS 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 10 mg/ml koncentrárum oldatos infúzióhoz	not available	OGYI-T-4721/02	SAS PIERRE FABRE MEDICAMENT	HU
NAVELBINE 50 mg/5 ml, solution injectable en flacon	not available	0724/04048619	PIERRE FABRE MEDICAMENT	LU
NAVELBINE 30 mg capsule moi	not available	6076/2005/02	PIERRE FABRE MEDICAMENT	RO
NAVELBINE 10 mg/ml concentrato per soluzione per infusione	not available	027865094	PFM PHARMA / ITALY	IT
NAVELBINE 20 mg capsule moi	not available	6075/2005/02	PIERRE FABRE MEDICAMENT	RO
Navelbine 40 mg/4 ml solution à diluer pour perfusion	not available	BE177597	SAS PIERRE FABRE MEDICAMENT	BE
Navelbine 10 mg/1 ml solution à diluer pour perfusion	not available	BE177606	SAS PIERRE FABRE MEDICAMENT	BE
Navelbine 40 mg/4 ml concentraat voor oplossing voor intraveneuze infusie	not available	BE177597	SAS PIERRE FABRE MEDICAMENT	BE
Navelbine 10 mg/1 ml concentraat voor oplossing voor intraveneuze infusie	not available	BE177606	SAS PIERRE FABRE MEDICAMENT	BE

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 10 mg/ml, ενέσιμο διάλυμα	not available	41576/23-9-2008	PIERRE FABRE FARMAKA SA	GR
Navelbine 10 mg/ml, ενέσιμο διάλυμα	not available	41578/23-9-2008	PIERRE FABRE FARMAKA SA	GR
Navelbine 10 mg/ml concentrat pentru soluție perfuzabilă	not available	4661/2012/02	SAS PIERRE FABRE MEDICAMENT	RO
Navelbine 10 mg/ml concentrat pentru soluție perfuzabilă	not available	4661/2012/03	SAS PIERRE FABRE MEDICAMENT	RO
NAVELBINE 10 mg/1 ml, solution injectable en flacon	not available	0724/04048618	PIERRE FABRE MEDICAMENT	LU
Навелбин 10 mg/ml концентрат за инфузионен разтвор	not available	20020969	PIERRE FABRE MEDICAMENT	BG
Navelbine, 10 mg/ml, koncentrat do sporządzania roztworu do infuzji	not available	R/1736	SAS PIERRE FABRE MEDICAMENT	PL
Navelbine 10 mg/ml concentrat pentru soluție perfuzabilă	not available	4661/2012/01	SAS PIERRE FABRE MEDICAMENT	RO
Навелбин 20 mg меки капсули	not available	20100098	PIERRE FABRE MEDICAMENT	BG
Navelbine 20 mg lágy kapszula	not available	OGYI-T-472 1/03	PIERRE FABRE MEDICAMENT	HU
Навелбин 30 mg меки капсули	not available	20100099	PIERRE FABRE MEDICAMENT	BG
Navelbine 30 mg lágy kapszula	not available	OGYI-T-4721/04	PIERRE FABRE MEDICAMENT	HU
Navelbine 30 mg mjúk hylki	not available	IS/1/03/135/02	PIERRE FABRE PHARMA NORDEN AB/SW	IS
Navelbine 80 mg mjúk hylki	not available	IS/1/03/135/04	PIERRE FABRE PHARMA NORDEN AB/SW	IS

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 10 mg/ml innrennslispykkni, lausn	not available	960118	PIERRE FABRE PHARMA NORDEN AB/SW	IS
Navelbine 20 mg mjúk hylki	not available	IS/1/03/135/01	PIERRE FABRE PHARMA NORDEN AB/SW	IS
Navelbine 10 mg/ml infuusiokonsentraatti, liuosta varten	not available	12191	PIERRE FABRE PHARMA NORDEN AB	FI
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/SW	FI
NAVELBINE ® 40 mg kapseli, pehmeä	not available	15884	PIERRE FABRE PHARMA NORDEN AB/SW	FI
NAVELBINE ® 80 mg kapseli, pehmeä	not available	15885	PIERRE FABRE PHARMA NORDEN AB/SW	FI
NAVELBINE 10 mg / ml concentrate for solution for infusion	not available	PA 1287/001/005	PIERRE FABRE LIMITED / UK	IE
NAVELBINE® 20 mg soft capsule	not available	PA 1287/001/001	PIERRE FABRE LIMITED	IE
NAVELBINE® 30 mg soft capsule	not available	PA 1287/001/002	PIERRE FABRE LIMITED	IE
NAVELBINE® 80 mg soft capsule	not available	PA 1287/001/004	PIERRE FABRE LIMITED / UK	IE
NAVELBINE 10 mg / 1 ml Konzentrat zur Herstellung einer Infusionslösung	not available	33071.00.00	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 80 mg Weichkapseln	not available	50133.03.00	PIERRE FABRE PHARMA GMBH	DE

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 50 mg / 5 ml Konzentrat zur Herstellung einer Infusionslösung	not available	33071.02.00	PIERRE FABRE PHARMA GMBH	DE
NAVELBINE 20 mg, capsule molle	not available	34009 365 948 4 5	SAS PIERRE FABRE MEDICAMENT	FR
NAVELBINE 30 mg, capsule molle	not available	34009 365 949 0 6	SAS PIERRE FABRE MEDICAMENT	FR
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	SAS PIERRE FABRE MEDICAMENT	FR
NAVELBINE 10 mg/1 ml, solution injectable en flacon	not available	34009 331 904 4 6	SAS PIERRE FABRE MEDICAMENT	FR
NAVELBINE 50 mg/5 ml, solution injectable en flacon	not available	34009 331 844 1 4	SAS PIERRE FABRE MEDICAMENT	FR
NAVELBINE 50 mg/5 ml concentrado para solución para perfusión	not available	59.299	PIERRE FABRE IBERICA, S.A.	ES
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 10 mg/ml concentrado para solución para perfusión	not available	59.300	PIERRE FABRE IBERICA, S.A.	ES
Navelbine 10 mg/ml koncentratas infuziniam tirpalui	not available	LT/1/97/2874/001	SAS PIERRE FABRE MEDICAMENT	LT
NAVELBINE 20 mg minkštosios kapsulės	not available	LT/1/97/2874/005	SAS PIERRE FABRE MEDICAMENT	LT

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 30 mg minkštosios kapsulės	not available	LT/1/97/2874/006	SAS PIERRE FABRE MEDICAMENT	LT
Navelbine 10 mg/ml koncentratas infuziniam tirpalui	not available	LT/1/97/2874/002	SAS PIERRE FABRE MEDICAMENT	LT
Navelbine 10 mg/ml koncentratas infuziniam tirpalui	not available	LT/1/97/2874/003	SAS PIERRE FABRE MEDICAMENT	LT
Navelbine 10 mg/ml koncentratas infuziniam tirpalui	not available	LT/1/97/2874/004	SAS PIERRE FABRE MEDICAMENT	LT
NAVELBINE® 20 mg soft capsule	not available	PL 00603/0029	PIERRE FABRE LIMITED	UK
NAVELBINE® 30 mg soft capsule	not available	PL 00603/0030	PIERRE FABRE LIMITED	UK
NAVELBINE® 80 mg soft capsule	not available	PL 00603/0032	PIERRE FABRE LIMITED	UK
NAVELBINE® 10 mg/ml concentrate for solution for infusion	not available	PL 00603/0028	PIERRE FABRE LIMITED	UK
NAVELBINE 20 mg pehmekapsel	not available	854914	SAS PIERRE FABRE MEDICAMENT	EE
NAVELBINE 30 mg pehmekapsel	not available	854814	SAS PIERRE FABRE MEDICAMENT	EE
Navelbine, 10 mg/ml infusioonilahuse kontsentraat	not available	310300	SAS PIERRE FABRE MEDICAMENT	EE
Navelbine® 10 mg - Infusionskonzentrat	not available	1-20425	SAS 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® 80 mg - Kapseln	not available	1-24693	PIERRE FABRE MEDICAMENT	AT
Navelbine® 40 mg - Infusionskonzentrat	not available	1-20427	PIERRE FABRE MEDICAMENT	AT

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® 50 mg - Infusionskonzentrat	not available	1-20428	PIERRE FABRE MEDICAMENT	AT
Navelbine 10mg/ml, concentrate for solution for infusion	not available	017884	GREGORIS HADJIGREGORIOU LTD	CY
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 infúzny koncentrát	not available	44/0136/92-S	PIERRE FABRE MEDICAMENT	SK
NAVELBINE 80 mg capsules, zacht	not available	RVG111395	PIERRE FABRE MEDICAMENT	NL
NAVELBINE 10 mg/ml, concentraat voor oplossing voor infusie	not available	RVG 18020	SAS PIERRE FABRE MEDICAMENT	NL
NAVELBINE 30 mg capsules, zacht	not available	RVG111394	PIERRE FABRE MEDICAMENT	NL
NAVELBINE 20 mg capsules, zacht	not available	RVG 111393	SAS PIERRE FABRE MEDICAMENT	NL
NAVELBINE koncentrát pro infuzní roztok	not available	44/ 136/ 92-S/C	PIERRE FABRE MEDICAMENT	CZ
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