



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 June 2020
EMA/422908/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: lenograstim

Procedure no.: PSUSA/00001839/201910

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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
wGRANOCYTE 34	not available	19158	SANOFI-AVENTIS CYPRUS LTD	CY
GRANOCYTE 34	not available	19158	SANOFI-AVENTIS CYPRUS LTD	CY
GRANOCYTE 34	not available	1w9158	SANOFI-AVENTIS CYPRUS LTD	CY
GRANOCYTE® 13 Millions UI/ml, poudre et solvant pour solution injectable/perfusion en seringue préremplie	FR/H/0044/001	34009349 757.38	CHUGAI PHARMA FRANCE	FR
GRANOCYTE® 13 Millions UI/ml, poudre et solvant pour solution injectable/perfusion	FR/H/0044/001	34009349 760.49	CHUGAI PHARMA FRANCE	FR
GRANOCYTE® 34 Millions UI/ml, poudre et solvant pour solution injectable / perfusion	FR/H/0044/002	34009349 808.79	CHUGAI PHARMA FRANCE	FR
GRANOCYTE® 34 Millions UI/ml, poudre et solvant pour solution injectable / perfusion en seringue préremplie	FR/H/0044/002	34009349 806.40	CHUGAI PHARMA FRANCE	FR

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
GRANOCYTE 13 million IU/mL, powder and solvent for solution for injection/infusion, in a pre-filled syringe	FR/H/0044/001	PA22641/002/002	CHUGAI PHARMA FRANCE	IE
GRANOCYTE 34 million IU/mL, powder and solvent for solution for injection/infusion, in a pre-filled syringe.	FR/H/0044/002	PA22641/002/001	CHUGAI PHARMA FRANCE	IE
GRANOCYTE® 13 Millionen IE/ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung in einer vorgefüllten Spritze Wirkstoff: Lenograstim	FR/H/0044/001	32083.01.00	CHUGAI PHARMA GERMANY GMBH	DE
GRANOCYTE® 13 Millionen IE/ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung Wirkstoff: Lenograstim	FR/H/0044/001	32083.01.00	CHUGAI PHARMA GERMANY GMBH	DE
GRANOCYTE® 34 Millionen IE/ml, Pulver und Lösungsmittel zur	FR/H/0044/002	28512.00.00	CHUGAI PHARMA GERMANY 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
Herstellung einer Injektions- oder Infusionslösung in einer vorgefüllten Spritze				
GRANOCYTE® 34 Millionen IE/ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	FR/H/0044/002	28512.00.00	CHUGAI PHARMA GERMANY GMBH	DE
GRANOCYTE 13 million IU/mL, powder and solvent for solution for injection/infusion in a pre-filled syringe.	FR/H/0044/001	PL 12185/0002	CHUGAI PHARMA UK LTD	UK
GRANOCYTE 34 million IU/mL, powder and solvent for solution for injection/infusion in a pre-filled syringe.	FR/H/0044/002	PL 12185/0002	CHUGAI PHARMA UK LTD	UK
GRANOCYTE 13 million IU/mL, powder and solvent for solution for injection/infusion.	FR/H/0044/001	PL 12185/0002	CHUGAI PHARMA UK LTD	UK
GRANOCYTE 34 million IU/mL, powder and solvent for solution for injection/infusion.	FR/H/0044/002	PL 12185/0002	CHUGAI PHARMA UK LTD	UK

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
GRANOCYTE® 13 Millions UI/ml, poudre et solvant pour solution injectable/perfusion	FR/H/0044/001	34009349 759.67	CHUGAI PHARMA FRANCE	FR
GRANOCYTE® 13 Millions UI/ml, poudre et solvant pour solution injectable/perfusion en seringue préremplie	FR/H/0044/001	34009349 756.77	CHUGAI PHARMA FRANCE	FR
GRANOCYTE® 34 Millions UI/ml, poudre et solvant pour solution injectable / perfusion	FR/H/0044/002	34009349 807.01	CHUGAI PHARMA FRANCE	FR
GRANOCYTE® 34 Millions UI/ml, poudre et solvant pour solution injectable / perfusion en seringue préremplie	FR/H/0044/002	34009349 761.00	CHUGAI PHARMA FRANCE	FR
Granocyte 13 Millionen IE/ml, Pulver und Lösungsmittel zur Herstellung einer Injektionslösung/Infusionslösung in einer Fertigspritze	FR/H/0044/001	BE178017	CHUGAI PHARMA FRANCE	BE
Granocyte 34 Millionen IE/ml, Pulver und Lösungsmittel zur	FR/H/0044/002	BE165724	CHUGAI PHARMA FRANCE	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
Herstellung einer Injektionslösung/Infusionslösung in einer Fertigspritze				
Granocyte 13 miljoen IE/ml, poeder en oplosmiddel voor oplossing voor injectie/infusie in een voorgevulde spuit	FR/H/0044/001	BE178017	CHUGAI PHARMA FRANCE	BE
Granocyte 34 miljoen IE/ml, poeder en oplosmiddel voor oplossing voor injectie/infusie in een voorgevulde spuit	FR/H/0044/002	BE165724	CHUGAI PHARMA FRANCE	BE
GRANOCYTE 13 millions UI/mL, poudre et solvant pour solution injectable/pour perfusion dans une seringue préremplie	FR/H/0044/001	1975/09010070 (0246421 - 0246403)	CHUGAI PHARMA FRANCE	LU
Granocyte 34 millions UI/ml, poudre et solvant pour solution injectable/pour perfusion dans une seringue préremplie	FR/H/0044/002	1975/09010071 (0246434 - 0246417)	CHUGAI PHARMA FRANCE	LU

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
Granocyte 13 millions UI/ml, poudre et solvant pour solution injectable/pour perfusion dans une seringue préremplie	FR/H/0044/001	BE178017	CHUGAI PHARMA FRANCE	BE
Granocyte 34 millions UI/ml, poudre et solvant pour solution injectable/pour perfusion dans une seringue préremplie	FR/H/0044/002	BE165724	CHUGAI PHARMA FRANCE	BE
Granocyte, 34 miljoner IE/ml, pulver och vätska till injektions- eller infusionsvätska, lösning.	FR/H/0044/002	11846	SANOFI AB	SE
Granocyte, 34 miljoner IE/ml, pulver och vätska till injektions- eller infusionsvätska, lösning.	FR/H/0044/002	11846	SANOFI AB	SE
GRANOCYTE 13 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione	FR/H/0044/001	028686083	ITALFARMACO S.P.A	IT
GRANOCYTE 13 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione	FR/H/0044/001	028686071	ITALFARMACO S.P.A	IT

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
GRANOCYTE 13 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione in siringa preriempita	FR/H/0044/001	028686069	ITALFARMACO S.P.A	IT
GRANOCYTE 13 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione in siringa preriempita	FR/H/0044/001	028686057	ITALFARMACO S.P.A	IT
GRANOCYTE 34 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione	FR/H/0044/002	028686018	ITALFARMACO S.P.A	IT
GRANOCYTE 34 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione	FR/H/0044/002	028686020	ITALFARMACO S.P.A	IT
GRANOCYTE 34 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione in siringa preriempita	FR/H/0044/002	028686044	ITALFARMACO S.P.A	IT
GRANOCYTE 34 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione in siringa preriempita	FR/H/0044/002	028686032	ITALFARMACO S.P.A	IT

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
GRANOCYTE 34 milhões de UI/mL, pó e solvente para solução injetável ou para perfusão.	FR/H/0044/002	2439180	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
GRANOCYTE 13 milj. IU/ml injektio- /infuusiokuiva-aine ja liuotin, liuosta varten	FR/H/0044/001	11655	SANOFI OY	FI
GRANOCYTE	FR/H/0044/001	40555/15-6-2010	SANOFI-AVENTIS AEBE	GR
GRANOCYTE 34 milhões de UI/mL, pó e solvente para solução injetável ou para perfusão.	FR/H/0044/002	2439289	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
GRANOCYTE 13 εκατομμύρια IU/ml, κόνις και διαλύτης για παρασκευή ενέσιμου διαλύματος ή διαλύματος προς έγχυση	FR/H/0044/001	40555/15-6-2010	SANOFI-AVENTIS AEBE	GR
GRANOCYTE 13 milhões de UI/mL, pó e solvente para solução injetável ou para perfusão	FR/H/0044/001	2439081	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Granocyte, 34 miljoner IE/ml, pulver och vätska till injektions- eller	FR/H/0044/002	11846	SANOFI AB	SE

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
infusionsvätska, lösning.				
GRANOCYTE 13 milhões de UI/mL, pó e solvente para solução injetável ou para perfusão	FR/H/0044/001	2438984	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
GRANOCYTE 13 milhões de UI/mL, pó e solvente para solução injetável ou para perfusão	FR/H/0044/001	2323780	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
GRANOCYTE	FR/H/0044/001	40555/15-6-2010	SANOFI-AVENTIS AEBE	GR
GRANOCYTE 13 MILJ. IU/ML, INJEKTIO/INFUUSIOKUIV A-AINE JA LIUOTIN, LIUOSTA VARTEN	FR/H/0044/001	11655	SANOFI OY	FI
GRANOCYTE 13 milhões de UI/mL, pó e solvente para solução injetável ou para perfusão	FR/H/0044/001	2323582	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Granocyte, 34 miljoner IE/ml, pulver och vätska till injektions- eller infusionsvätska, lösning.	FR/H/0044/002	11846	SANOFI AB	SE

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
GRANOCYTE 13 MILJ. IU/ML, INJEKTIO/INFUUSIOKUIV A-AINE JA LIUOTIN, LIUOSTA VARTEN	FR/H/0044/001	11655	SANOFI OY	FI
GRANOCYTE 34 milhões de UI/mL, pó e solvente para solução injetável ou para perfusão.	FR/H/0044/002	2324887	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Granocyte, 34 miljoner IE/ml, pulver och vätska till injektions- eller infusionsvätska, lösning.	FR/H/0044/002	11846	SANOFI AB	SE
GRANOCYTE 13 MILJ. IU/ML, INJEKTIO/INFUUSIOKUIV A-AINE JA LIUOTIN, LIUOSTA VARTEN	FR/H/0044/001	11655	SANOFI OY	FI
GRANOCYTE	FR/H/0044/001	40555/15-6-2010	SANOFI-AVENTIS AEBE	GR
GRANOCYTE 34 milhões de UI/mL, pó e solvente para solução injetável ou para perfusão.	FR/H/0044/002	2213882	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
GRANOCYTE	FR/H/0044/002	14957	SANOFI-AVENTIS DENMARK A/S	DK

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GRANOCYTE	FR/H/0044/001	16876	SANOFI-AVENTIS DENMARK A/S	DK
GRANOCYTE	FR/H/0044/002	40554/15-6-2010	SANOFI-AVENTIS AEBE	GR
GRANOCYTE	FR/H/0044/002	40554/15-6-2010	SANOFI-AVENTIS AEBE	GR
GRANOCYTE 34 εκατομμύρια IU/ml, κόνις και διαλύτης για παρασκευή ενέσιμου διαλύματος ή διαλύματος προς έγχυση	FR/H/0044/002	22713/26-11-1993	SANOFI-AVENTIS AEBE	GR
GRANOCYTE 13 millones de UI/mL polvo y disolvente para solución inyectable/perfusión	FR/H/0044/001	60.672	ITALFARMACO S.A.	ES
GRANOCYTE 34 millones de UI/mL polvo y disolvente para solución inyectable/perfusión	FR/H/0044/002	60.211	ITALFARMACO S.A.	ES
MYELOSTIM 13 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione	not available	029059033	ITALFARMACO S.P.A	IT

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
MYELOSTIM 13 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione in siringa preriempita	not available	029059072	ITALFARMACO S.P.A	IT
MYELOSTIM 34 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione	not available	029059019	ITALFARMACO S.P.A	IT
MYELOSTIM 34 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione in siringa preriempita	not available	029059096	ITALFARMACO S.P.A	IT
MYELOSTIM 13 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione in siringa preriempita	not available	029059084	ITALFARMACO S.P.A	IT
MYELOSTIM 34 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione	not available	029059021	ITALFARMACO S.P.A	IT
MYELOSTIM 34 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione in siringa preriempita	not available	029059108	ITALFARMACO S.P.A	IT

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
MYELOSTIM 13 milioni UI/ml, polvere e solvente per soluzione iniettabile/infusione	not available	029059045	ITALFARMACO S.P.A	IT
GRANOCYTE 34 (33,6 milijono TV/ml) milteliai ir tirpiklis injekciniam ar infuziniam tirpalui	not available	LT/1/99/1427/002	UAB SANOFI-AVENTIS LIETUVA	LT
GRANOCYTE 34 (33,6 milijono TV/ml) milteliai ir tirpiklis injekciniam ar infuziniam tirpalui	not available	LT/1/99/1427/003	UAB SANOFI-AVENTIS LIETUVA	LT
GRANOCYTE 34 (33,6 milijono TV/ml) milteliai ir tirpiklis injekciniam ar infuziniam tirpalui	not available	LT/1/99/1427/004	UAB SANOFI-AVENTIS LIETUVA	LT
GRANOCYTE 34 (33,6 milijono TV/ml) milteliai ir tirpiklis injekciniam ar infuziniam tirpalui	not available	LT/1/99/1427/001	UAB SANOFI-AVENTIS LIETUVA	LT