



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam, 30 November 2023
EMA/560815/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: cytarabine

Procedure no.: PSUSA/00000911/202303



Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Alexan 100 mg/ml – Konzentrat zur Herstellung einer Infusionslösung	not available	1-26628	EBEWE PHARMA	AT
Alexan 20 mg/ml – Stechampulle	not available	1-18202	EBEWE PHARMA	AT
Alexan 50 mg/ml – Stechampulle	not available	1-19118	EBEWE PHARMA	AT
ARACYTIN	not available	22798/19.6.95	PFIZER HELLAS, A.E.	GR
ARACYTIN	not available	23263/21.6.95	PFIZER HELLAS, A.E.	GR
ARACYTIN 100 mg/5 ml Polvere e Solvente per Soluzione Iniettabile	not available	022391015	PFIZER ITALIA S.R.L.	IT
ARACYTIN 500 mg/10 ml Polvere e Solvente per Soluzione Iniettabile	not available	022391039	PFIZER ITALIA S.R.L.	IT
ARACYTINE 1 g, poudre pour solution pour perfusion (I.V.)	not available	34009 555 784 2 0	PFIZER HOLDING FRANCE	FR
ARACYTINE 1 g, poudre pour solution pour perfusion (I.V.)	not available	34009 562 016 7 9	PFIZER HOLDING FRANCE	FR
ARACYTINE 100 mg, poudre et solvant pour solution injectable	not available	34009 553 151 2 4	PFIZER HOLDING FRANCE	FR

ARACYTINE 100 mg, poudre et solvant pour solution injectable	not available	34009 302 672 1 9	PFIZER HOLDING FRANCE	FR
ARACYTINE 2 g, poudre pour solution pour perfusion (I.V.)	not available	34009 555 785 9 8	PFIZER HOLDING FRANCE	FR
ARACYTINE 2 g, poudre pour solution pour perfusion (I.V.)	not available	34009 562 648 3 4	PFIZER HOLDING FRANCE	FR
ARACYTINE 500 mg, poudre pour solution pour perfusion	not available	34009 555 305 7 2	PFIZER HOLDING FRANCE	FR
ARACYTINE 500 mg, poudre pour solution pour perfusion	not available	34009 562 015 0 1	PFIZER HOLDING FRANCE	FR
Citaloxan 100 mg/ml Solução injetável Citarabina	not available	5043187	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Citaloxan 100 mg/ml Solução injetável Citarabina	not available	2158780	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Citaloxan 100 mg/ml Solução injetável Citarabina	not available	2158889	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Citaloxan 20 mg/ml Solução injetável Citarabina	not available	3322385	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Citaloxan 20 mg/ml Solução injetável Citarabina	not available	3322286	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT

Citarabina Accord 100 mg/ml solución inyectable y para perfusión	not available	74455	ACCORD HEALTHCARE S.L.U.	ES
Citarabina Accord 100 mg/ml solución inyectable y para perfusión	not available	74455	ACCORD HEALTHCARE S.L.U.	ES
Citarabina Accord 100 mg/ml solución inyectable y para perfusión	not available	74455	ACCORD HEALTHCARE S.L.U.	ES
Citarabina Accord 100 mg/ml solución inyectable y para perfusión	not available	74455	ACCORD HEALTHCARE S.L.U.	ES
Citarabina Accord 100 mg/ml solución inyectable y para perfusión	not available	74455	ACCORD HEALTHCARE S.L.U.	ES
Citarabina Accord 100 mg/ml solución inyectable y para perfusión	not available	74455	ACCORD HEALTHCARE S.L.U.	ES
Citarabina Accord 100 mg/ml soluzione iniettabile o per infusione	NL/H/4561/001	042356067	ACCORD HEALTHCARE S.L.U.	IT
Citarabina Accord 100 mg/ml soluzione iniettabile o per infusione	NL/H/4561/001	042356016	ACCORD HEALTHCARE S.L.U.	IT

Citarabina Accord 100 mg/ml soluzione iniettabile o per infusione	NL/H/4561/001	042356028	ACCORD HEALTHCARE S.L.U.	IT
Citarabina Accord 100 mg/ml soluzione iniettabile o per infusione	NL/H/4561/001	042356030	ACCORD HEALTHCARE S.L.U.	IT
Citarabina Accord 100 mg/ml soluzione iniettabile o per infusione	NL/H/4561/001	042356055	ACCORD HEALTHCARE S.L.U.	IT
Citarabina Accord 100 mg/ml soluzione iniettabile o per infusione	NL/H/4561/001	042356042	ACCORD HEALTHCARE S.L.U.	IT
Citarabina Accord 100 mg/ml soluzione iniettabile o per infusione	NL/H/4561/001	042356079	ACCORD HEALTHCARE S.L.U.	IT
Citarabina Accord 100 mg/ml soluzione iniettabile o per infusione	NL/H/4561/001/DC	042356081	ACCORD HEALTHCARE S.L.U.	IT
Citarabina Accord 20 mg/ml solución inyectable y para perfusión	FI/H/1038/001	83265	ACCORD HEALTHCARE S.L.U.	ES
Citarabina Accord 20 mg/ml solución inyectable y para perfusión	FI/H/1038/001	83265	ACCORD HEALTHCARE S.L.U.	ES

Citarabina Kabi 100 mg/ml solución inyectable o para perfusión	PT/H/2328/001	77.352	FRESENIUS KABI ESPAÑA S.A.U.	ES
Citarabina Pfizer 100 mg polvo y disolvente para solución inyectable y para perfusión	not available	49.154	PFIZER, S.L.	ES
Citarabina Pfizer 20 mg/ml solución inyectable y para perfusión	not available	86180	PFIZER, S.L.	ES
Citarabina Pfizer 20 mg/ml solución inyectable y para perfusión	not available	86180	PFIZER, S.L.	ES
Citarabina Pfizer 500 mg polvo y disolvente para solución inyectable y para perfusión	not available	56.463	PFIZER, S.L.	ES
Cytarabin Fresenius Kabi	PT/H/2328/001	48669	FRESENIUS KABI AB	DK
Cytarabine "Accord", injektions-/infusionsvæske, opløsning 100 mg/ml	NL/H/4561/001	51562	ACCORD HEALTHCARE B.V.	DK
Cytarabine "Accord", injektions-/infusionsvæske, opløsning 100 mg/ml	NL/H/4561/001	51562	ACCORD HEALTHCARE B.V.	DK
Cytarabine "Accord", injektions-/infusionsvæske, opløsning 100 mg/ml	NL/H/4561/001	51562	ACCORD HEALTHCARE B.V.	DK

Cytarabine "Accord", injektions-/infusionsvæske, opløsning 100 mg/ml	NL/H/4561/001	51562	ACCORD HEALTHCARE B.V.	DK
Cytarabine "Accord", injektions-/infusionsvæske, opløsning 100 mg/ml	NL/H/4561/001	51562	ACCORD HEALTHCARE B.V.	DK
Cytarabine "Accord", injektions-/infusionsvæske, opløsning 100 mg/ml	NL/H/4561/001	51562	ACCORD HEALTHCARE B.V.	DK
Cytarabine "Pfizer", injektions-/infusionsvæske, opløsning	not available	15911	PFIZER APS	DK
Cytarabine "Pfizer", injektions-/infusionsvæske, opløsning	not available	15912	PFIZER APS	DK
Cytarabine „Pfizer“ 100 mg/ml stungulyf/innrennslyf, lausn.	not available	940026	PFIZER APS	IS
Cytarabine „Pfizer“ 20 mg/ml stungulyf/innrennslyf, lausn.	not available	940025	PFIZER APS	IS
Cytarabine 100mg/ml solution for infusion or injection	not available	PL 00057/0955	PFIZER LIMITED	XI
CYTARABINE ACCORD 100 mg/ml, solution injectable ou pour perfusion	NL/H/4561/001	34009 585 317 3 6	ACCORD HEALTHCARE FRANCE SAS	FR
CYTARABINE ACCORD 100 mg/ml, solution injectable ou pour perfusion	NL/H/4561/001	34009 585 313 8 5	ACCORD HEALTHCARE FRANCE SAS	FR

CYTARABINE ACCORD 100 mg/ml, solution injectable ou pour perfusion	NL/H/4561/001	34009 585 314 4 6	ACCORD HEALTHCARE FRANCE SAS	FR
CYTARABINE ACCORD 100 mg/ml, solution injectable ou pour perfusion	NL/H/4561/001	34009 585 315 0 7	ACCORD HEALTHCARE FRANCE SAS	FR
CYTARABINE ACCORD 100 mg/ml, solution injectable ou pour perfusion	NL/H/4561/001	34009 585 316 7 5	ACCORD HEALTHCARE FRANCE SAS	FR
CYTARABINE ACCORD 100 mg/ml, solution injectable ou pour perfusion	NL/H/4561/001	34009 585 319 6 5	ACCORD HEALTHCARE FRANCE SAS	FR
CYTARABINE ACCORD 100 mg/ml, solution injectable ou pour perfusion	NL/H/4561/001	34009 550 281 6 1	ACCORD HEALTHCARE FRANCE SAS	FR
CYTARABINE ACCORD 100 mg/ml, solution injectable ou pour perfusion	NL/H/4561/001	34009 550 281 7 8	ACCORD HEALTHCARE FRANCE SAS	FR
CYTARABINE KABI 100 mg/ml, solution injectable ou pour perfusion	PT/H/2328/001	34009 582 855 4 7	FRESENIUS KABI FRANCE S.A.S.	FR
CYTARABINE KABI 100 mg/ml, solution injectable ou pour perfusion	PT/H/2328/001	34009 582 852 5 7	FRESENIUS KABI FRANCE S.A.S.	FR

CYTARABINE KABI 100 mg/ml, solution injectable ou pour perfusion	PT/H/2328/001	34009 582 853 1 8	FRESENIUS KABI FRANCE S.A.S.	FR
CYTARABINE KABI 100 mg/ml, solution injectable ou pour perfusion	PT/H/2328/001	34009 582 854 8 6	FRESENIUS KABI FRANCE S.A.S.	FR
CYTARABINE SANDOZ 100 mg/ml, solution injectable	not available	34009 580 861 7 5	SANDOZ	FR
CYTARABINE SANDOZ 100 mg/ml, solution injectable	not available	34009 580 862 3 6	SANDOZ	FR
CYTARABINE SANDOZ 20 mg/ml, solution injectable	not available	34009 330 843 1 8	SANDOZ	FR
CYTARABINE SANDOZ 20 mg/ml, solution injectable	not available	34009 380 499 2 3	SANDOZ	FR
CYTARABINE SANDOZ 20 mg/ml, solution injectable	not available	34009 380 500 0 4	SANDOZ	FR
CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 556 064 3 7	SANDOZ	FR
CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 556 066 6 6	SANDOZ	FR
CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 556 068 9 5	SANDOZ	FR
CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 556 070 3 8	SANDOZ	FR

CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 571 029 0 6	SANDOZ	FR
CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 571 030 9 5	SANDOZ	FR
CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 571 408 1 6	SANDOZ	FR
CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 571 409 8 4	SANDOZ	FR
CYTARABINE SANDOZ 50 mg/ml, solution injectable	not available	34009 571 410 6 6	SANDOZ	FR
Cytosar 1 g Konzentrat zur Herstellung einer Infusionslösung	not available	2007079392	PFIZER S.A.	LU
Cytosar 1 g por oldatos injekcióhoz	not available	OGYI-T-2093/03	PFIZER KFT.	HU
Cytosar 1 g prašak za otopinu za injekciju / infuziju	not available	HR-H-301692413	PFIZER CROATIA D.O.O.	HR
Cytosar 1 g prašek za raztopino za injiciranje/infundiranje	not available	H/92/00433/001	PFIZER LUXEMBOURG S.À.R.L.	SI
CYTOSAR 1 g prášok na injekčný roztok	not available	44/0314/18-S	PFIZER EUROPE MA EEIG	SK
CYTOSAR 1 g, concentraat voor oplossing voor infusie	not available	BE 176601	PFIZER S.A. (BELGIUM)	BE

CYTOSAR 100 mg prášek a rozpouštěadlo na injekčný roztok	not available	44/0640/70-CS	PFIZER EUROPE MA EEIG	SK
CYTOSAR 100 mg, solution injectable	not available	BE 176565	PFIZER S.A. (BELGIUM)	BE
CYTOSAR 100 mg, solution injectable	not available	2007079390	PFIZER S.A. (BELGIUM)	LU
CYTOSAR 2 g, concentraat voor oplossing voor infusie	not available	BE 176617	PFIZER S.A. (BELGIUM)	BE
CYTOSAR 2 g, solution à diluer pour perfusion	not available	2007079393	PFIZER S.A. (BELGIUM)	LU
Cytosar 20 mg/ml por és oldószer oldatos injekcióhoz	not available	OGYI-T-2093/02	PFIZER KFT.	HU
Cytosar 50 mg/ml por és oldószer oldatos injekcióhoz	not available	OGYI-T-2093/01	PFIZER KFT.	HU
CYTOSAR 500 mg prášek a rozpouštěadlo na injekčný roztok	not available	44/0313/18-S	PFIZER EUROPE MA EEIG	SK
CYTOSAR 500 mg, oplossing voor injectie	not available	BE 176574	PFIZER S.A. (BELGIUM)	BE
CYTOSAR 500 mg, solution injectable	not available	2007079391	PFIZER S.A. (BELGIUM)	LU
CYTOSAR, 1 g, proszek do sporządzania roztworu do wstrzykiwań	not available	R/3146	PFIZER EUROPE MA EEIG	PL

CYTOSAR, 100 mg, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań	not available	R/1547	PFIZER EUROPE MA EEIG	PL
CYTOSAR, 100 mg/ml, roztwór do wstrzykiwań/ do infuzji	not available	27034	PFIZER EUROPE MA EEIG	PL
Cytosar, 1000 mg süstelähuse pulber	not available	055694	PFIZER EUROPE MA EEIG	EE
CYTOSAR, 20 mg/ml, roztwór do wstrzykiwań/ do infuzji	not available	27033	PFIZER EUROPE MA EEIG	PL
CYTOSAR, 20 mg/ml, roztwór do wstrzykiwań/ do infuzji	not available	27033	PFIZER EUROPE MA EEIG	PL
CYTOSAR, 500 mg, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań	not available	R/3145	PFIZER EUROPE MA EEIG	PL
АЛЕКСАН 50 МГ/МЛ ИНЖЕКЦИОНЕН РАСТВОР	not available	20050472	EBEWE PHARMA	BG