



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2022
EMA/794442/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): gentamicin (implant)

Procedure No. PSUSA/00010628/202203



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
Septopal-Kette zur Implantation	not available	16.971	ZIMMER BIOMET AUSTRIA GMBH	AT
Sulmycin Implant-Schwamm	not available	1-20152	SERB SA	AT
Sulmycin Implant-Schwamm	not available	1-20152	SERB SA	AT
Sulmycin Implant-Schwamm	not available	1-20152	SERB SA	AT
Septopal-Minikette zur Implantation	not available	1-19738	ZIMMER BIOMET AUSTRIA GMBH	AT
DURACOLL, 130 mg implant (10 cm x 10 cm x 0,5 cm)	not available	BE166013	SERB SA	BE
DURACOLL, 32,5 mg implant (5 cm x 5 cm x 0,5 cm)	not available	BE166004	SERB SA	BE
DURACOLL, 130 mg implantaat (10 cm x 10 cm x 0,5 cm)	not available	BE166013	SERB SA	BE
DURACOLL, 32,5 mg implantaat (5 cm x 5 cm x 0,5 cm)	not available	BE166004	SERB SA	BE
Duracoll 130 mg Implantat	not available	BE166013	SERB SA	BE
Duracoll 32,5 mg Implantat	not available	BE166004	SERB SA	BE
Garamycin Schwamm 130 mg Lécivá hubka	not available	15/005/89-S/C	SERB SA	CZ
Septopal®- 60er-Kette	not available	2.00.03	ZIMMER BIOMET DEUTSCHLAND GMBH	DE
Septopal®- 30er-Kette	not available	2.00.01	ZIMMER BIOMET DEUTSCHLAND GMBH	DE
Septopal®-10er-Kette	not available	2.00.02	ZIMMER BIOMET DEUTSCHLAND GMBH	DE
Septopal®-10er-Minikette	not available	2.00.04	ZIMMER BIOMET DEUTSCHLAND GMBH	DE
Septopal®- 20er-Minikette	not available	2.00.05	ZIMMER BIOMET DEUTSCHLAND GMBH	DE
Sulmycin® Implant E	not available	6560.00.01	SERB SA	DE
Sulmycin® Implant E	not available	6560.00.01	SERB SA	DE
Sulmycin® Implant E	not available	6560.00.01	SERB SA	DE
Gentacoll, implantat	not available	13644	SERB SA	DK
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Gentacoll, implantat	not available	13644	SERB SA	DK
Gentacoll 1,3 mg/cm ² implantaatti	NL/H/0126/002	11730	SERB SA	FI
Gentacoll 1,3 mg/cm ² implantaatti	NL/H/0126/001	11730	SERB SA	FI
Gentacoll 1,3 mg/cm ² implantaatti	NL/H/0126/001	11730	SERB SA	FI
Gentacoll 1,3 mg/cm ² implantat	not available	11730	SERB SA	FI
Gentacoll vefjalyf.	not available	930140	SERB SA	IS
Gentacoll vefjalyf.	not available	930140	SERB SA	IS
Gentacoll vefjalyf.	not available	930140	SERB SA	IS
DURACOLL, 130 mg implant (10 cm x 10 cm x 0,5 cm)	not available	2009070402	SERB SA	LU
DURACOLL, 32,5 mg implant (5 cm x 5 cm x 0,5 cm)	not available	2009070401	SERB SA	LU
Duracoll 130 mg Implantat	not available	2009070402	SERB SA	LU
Duracoll 32,5 mg Implantat	not available	2009070401	SERB SA	LU
GARACOL® 32.5mg	not available	RVG 20153	SERB SA	NL
GARACOL® 130mg	N/A	RVG 15815	SERB SA	NL
GARACOL® 130mg	N/A	RVG 15815	SERB SA	NL
Septopal miniketting 2,8 mg, implantatieketting	not available	RVG 12500	ZIMMER BIOMET NEDERLAND BV	NL
Septopal ketting 7,5 mg, implantatieketting	not available	RVG 07618	ZIMMER BIOMET NEDERLAND BV	NL
Garamycin, gabka, 2 mg/cm ²	not available	R/3222	SERB SA	PL
Garamycin, gabka, 2 mg/cm ²	not available	R/3222	SERB SA	PL
Garamycin, gabka, 2 mg/cm ²	not available	R/3222	SERB SA	PL
Garamycin, gabka, 2 mg/cm ²	not available	R/3222	SERB SA	PL
Garamycin, gabka, 2 mg/cm ²	not available	R/3222	SERB SA	PL
Garamycin, gabka, 2 mg/cm ²	not available	R/3222	SERB SA	PL
CRONOCOL, 32,5 mg, implante	NL/H/0126/002	2560886	SERB SA	PT
CRONOCOL, 32,5 mg, implante	NL/H/0126/002	2560985	SERB SA	PT
CRONOCOL, 32,5 mg, implante	NL/H/0126/002	2561082	SERB SA	PT
CRONOCOL, 130 mg, implante	NL/H/0126/001	2561280	SERB SA	PT

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CRONOCOL, 130 mg, implante	NL/H/0126/001	5044714	SERB SA	PT
CRONOCOL, 130 mg, implante	NL/H/0126/001	5044722	SERB SA	PT
GARAMYCIN SCHWAMM 10 x 10 x 0,5 cm	not available	15/0005/89-S	SERB SA	SK