



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 July 2025
EMADOC-1700519818-3339455
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): sufentanil

EURD list No. PSUSA/00002798/202411



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
Dzuveo 30 micrograms sublingual tablet	EMA/H/C/004335	EU/1/18/1284/001	LABORATOIRE AGUETTANT	IS
Dzuveo 30 micrograms sublingual tablet	EMA/H/C/004335	EU/1/18/1284/002	LABORATOIRE AGUETTANT	IS
Dzuveo 30 micrograms sublingual tablet	EMA/H/C/004335	EU/1/18/1284/001	LABORATOIRE AGUETTANT	LI
Dzuveo 30 micrograms sublingual tablet	EMA/H/C/004335	EU/1/18/1284/002	LABORATOIRE AGUETTANT	LI
Dzuveo 30 micrograms sublingual tablet	EMA/H/C/004335	EU/1/18/1284/001	LABORATOIRE AGUETTANT	NO
Dzuveo 30 micrograms sublingual tablet	EMA/H/C/004335	EU/1/18/1284/002	LABORATOIRE AGUETTANT	NO
Dzuveo 30 micrograms sublingual tablet	not available	PLGB 14434/0051	LABORATOIRE AGUETTANT	XI
Dzuveo 30 micrograms sublingual tablet	not available	PLGB 14434/0051	LABORATOIRE AGUETTANT	XI
Sufenta - Ampullen	not available	1-18247	PIRAMAL CRITICAL CARE B.V.	AT
Sufenta - Ampullen	not available	1-18247	PIRAMAL CRITICAL CARE B.V.	AT
Sufenta - Ampullen	not available	1-18247	PIRAMAL CRITICAL CARE B.V.	AT
Sufenta 0,005 mg/ml Solução injetável	not available	8596304	PIRAMAL CRITICAL CARE B.V.	PT
Sufenta 0,005 mg/ml Solução injetável	not available	8596312	PIRAMAL CRITICAL CARE B.V.	PT
SUFENTA 10 microgrammes/2 ml, solution injectable (I.V. ou péridurale)	not available	34009 561 146 4 1	PIRAMAL CRITICAL CARE B.V.	FR
SUFENTA 250 microgrammes/5 ml, solution injectable (I.V. ou péridurale) en ampoule	not available	34009 557 246 8 1	PIRAMAL CRITICAL CARE B.V.	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
SUFENTA 5 mikrog/ml injektionsvätska, lösning	not available	11174	PIRAMAL CRITICAL CARE B.V.	FI
SUFENTA 5 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111447	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111447	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta 5 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111447	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	BE 111447	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	BE 111447	PIRAMAL CRITICAL CARE B.V.	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
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	BE 111447	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	2005058755	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	2005058755	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	2005058754	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	2005058754	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	2005058755	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA 5 microgrammes/ml (mcg/ml) solution injectable	not available	2005058754	PIRAMAL CRITICAL CARE B.V.	LU
Sufenta 5 mikrog/ml injeksjonsvæske, oppløsning	not available	7846	PIRAMAL CRITICAL CARE B.V.	NO
Sufenta 5 mikrog/ml	not available	7846	PIRAMAL CRITICAL CARE	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
injeksjonsvæske, oppløsning			B.V.	
Sufenta 5 mikrog/ml injeksjonsvæske, oppløsning	not available	7846	PIRAMAL CRITICAL CARE B.V.	NO
Sufenta 5 mikrog/ml injeksjonsvæske, oppløsning	not available	7846	PIRAMAL CRITICAL CARE B.V.	NO
SUFENTA 5 mikrog/ml injektioneste, liuos	not available	11174	PIRAMAL CRITICAL CARE B.V.	FI
SUFENTA 5 mikrog/ml injektioneste, liuos	not available	11174	PIRAMAL CRITICAL CARE B.V.	FI
Sufenta 5 mikrog/ml injektionsvätska, lösning	not available	11174	PIRAMAL CRITICAL CARE B.V.	FI
Sufenta 5 mikróg/ml stungulyf, lausn.	not available	900146	PIRAMAL CRITICAL CARE B.V.	IS
Sufenta 5 mikrogram/ml injektionsvæske, opløsning	not available	13894	PIRAMAL CRITICAL CARE B.V.	DK
Sufenta 5 mikrogram/ml injektionsvæske, opløsning	not available	13894	PIRAMAL CRITICAL CARE B.V.	DK
Sufenta 5 mikrogram/ml injektionsvæske, opløsning	not available	13894	PIRAMAL CRITICAL CARE B.V.	DK
Sufenta 5 mikrogram/ml injektionsvätska, lösning	not available	11421	PIRAMAL CRITICAL CARE B.V.	SE
Sufenta 5 mikrogram/ml injektionsvätska, lösning	not available	11421	PIRAMAL CRITICAL CARE B.V.	SE
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta 5	not available	BE 111447	PIRAMAL CRITICAL CARE	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
Mikrogramm/ml Injektionslösung			B.V.	
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	BE 111447	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	BE 111431	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	BE 111447	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	2005058755	PIRAMAL CRITICAL CARE B.V.	LU
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	2005058755	PIRAMAL CRITICAL CARE B.V.	LU
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	2005058754	PIRAMAL CRITICAL CARE B.V.	LU
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	2005058754	PIRAMAL CRITICAL CARE B.V.	LU
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	2005058755	PIRAMAL CRITICAL CARE B.V.	LU
Sufenta 5 Mikrogramm/ml Injektionslösung	not available	2005058754	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA 5 mikrogramů/ml injekční roztok	not available	65/309/91-A/C	PIRAMAL CRITICAL CARE B.V.	CZ
SUFENTA 50 microgrammes/10 ml, solution injectable (I.V. ou péridurale)	not available	34009 561 147 0 2	PIRAMAL CRITICAL CARE B.V.	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
Sufenta 50 mikrogram/ml injektionsvätska, lösning	not available	11422	PIRAMAL CRITICAL CARE B.V.	SE
Sufenta 50 mikrogram/ml injektionsvätska, lösning	not available	11422	PIRAMAL CRITICAL CARE B.V.	SE
Sufenta epidural, 5 Mikrogramm/ml Injektionslösung	not available	27475.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta epidural, 5 Mikrogramm/ml Injektionslösung	not available	27475.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta epidural, 5 Mikrogramm/ml Injektionslösung	not available	27475.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta Forte 0,05 mg/ml Solução injetável	not available	8596338	PIRAMAL CRITICAL CARE B.V.	PT
Sufenta Forte 0,05 mg/ml Solução injetável	not available	8596320	PIRAMAL CRITICAL CARE B.V.	PT
SUFENTA FORTE 50 mikrog/ml injektionsvätska, lösning	not available	11175	PIRAMAL CRITICAL CARE B.V.	FI
SUFENTA FORTE 50 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111456	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA FORTE 50 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111456	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA FORTE 50 microgram/ml (mcg/ml) oplossing voor injectie	not available	BE 111456	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA FORTE 50 microgrammes/ml (mcg/ml) solution injectable	not available	BE 111456	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA FORTE 50	not available	BE 111456	PIRAMAL CRITICAL CARE	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
microgrammes/ml (mcg/ml) solution injectable			B.V.	
SUFENTA FORTE 50 microgrammes/ml (mcg/ml) solution injectable	not available	BE 111456	PIRAMAL CRITICAL CARE B.V.	BE
SUFENTA FORTE 50 microgrammes/ml (mcg/ml) solution injectable	not available	2005058756	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA FORTE 50 microgrammes/ml (mcg/ml) solution injectable	not available	2005058756	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA FORTE 50 microgrammes/ml (mcg/ml) solution injectable	not available	2005058756	PIRAMAL CRITICAL CARE B.V.	LU
Sufenta Forte 50 mikrog/ml injeksjonsvæske, oppløsning	not available	7847	PIRAMAL CRITICAL CARE B.V.	NO
Sufenta Forte 50 mikrog/ml injeksjonsvæske, oppløsning	not available	7847	PIRAMAL CRITICAL CARE B.V.	NO
Sufenta Forte 50 mikrog/ml injeksjonsvæske, oppløsning	not available	7847	PIRAMAL CRITICAL CARE B.V.	NO
Sufenta Forte 50 mikrog/ml injeksjonsvæske, oppløsning	not available	7847	PIRAMAL CRITICAL CARE B.V.	NO
SUFENTA FORTE 50	not available	11175	PIRAMAL CRITICAL CARE	FI

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
mikrog/ml injektioneste, liuos			B.V.	
SUFENTA FORTE 50 mikrog/ml injektioneste, liuos	not available	11175	PIRAMAL CRITICAL CARE B.V.	FI
Sufenta Forte 50 mikrog/ml injektionsvätska, lösning	not available	11175	PIRAMAL CRITICAL CARE B.V.	FI
Sufenta Forte 50 mikrogram/ml injektionsvæske, opløsning	not available	13895	PIRAMAL CRITICAL CARE B.V.	DK
Sufenta Forte 50 mikrogram/ml injektionsvæske, opløsning	not available	13895	PIRAMAL CRITICAL CARE B.V.	DK
Sufenta Forte 50 mikrogram/ml injektionsvæske, opløsning	not available	13895	PIRAMAL CRITICAL CARE B.V.	DK
Sufenta Forte 50 mikrogram/ml injektionsvæske, opløsning	not available	13895	PIRAMAL CRITICAL CARE B.V.	DK
Sufenta Forte 50 Mikrogramm/ml Injektionslösung	not available	BE 111456	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta Forte 50 Mikrogramm/ml Injektionslösung	not available	BE 111456	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta Forte 50 Mikrogramm/ml Injektionslösung	not available	BE 111456	PIRAMAL CRITICAL CARE B.V.	BE
Sufenta Forte 50 Mikrogramm/ml Injektionslösung	not available	2005058756	PIRAMAL CRITICAL CARE B.V.	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
Sufenta Forte 50 Mikrogramm/ml Injektionslösung	not available	2005058756	PIRAMAL CRITICAL CARE B.V.	LU
Sufenta Forte 50 Mikrogramm/ml Injektionslösung	not available	2005058756	PIRAMAL CRITICAL CARE B.V.	LU
SUFENTA FORTE 50 mikrogramů/ml injekční roztok	not available	65/309/91-B/C	PIRAMAL CRITICAL CARE B.V.	CZ
SUFENTA FORTE 50 mikrogramů/ml injekční roztok	not available	65/309/91-B/C	PIRAMAL CRITICAL CARE B.V.	CZ
Sufenta forte oplossing voor injectie 0,05 mg/ml.	not available	RVG 09232	PIRAMAL CRITICAL CARE B.V.	NL
Sufenta forte oplossing voor injectie 0,05 mg/ml.	not available	RVG 09232	PIRAMAL CRITICAL CARE B.V.	NL
Sufenta forte oplossing voor injectie 0,05 mg/ml.	not available	RVG 09232	PIRAMAL CRITICAL CARE B.V.	NL
Sufenta mite, 5 Mikrogramm/ml Injektionslösung	not available	7692.02.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta mite, 5 Mikrogramm/ml Injektionslösung	not available	7692.02.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta mite, 5 Mikrogramm/ml Injektionslösung	not available	7692.02.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta mite, 5 Mikrogramm/ml Injektionslösung	not available	7692.02.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta mite, 5 Mikrogramm/ml Injektionslösung	not available	7692.02.00	PIRAMAL CRITICAL CARE B.V.	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
Sufenta mite, 5 Mikrogramm/ml Injektionslösung	not available	7692.02.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta oplossing voor injectie 0,005 mg/ml.	not available	RVG 09233	PIRAMAL CRITICAL CARE B.V.	NL
Sufenta oplossing voor injectie 0,005 mg/ml.	not available	RVG 09233	PIRAMAL CRITICAL CARE B.V.	NL
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, 50 Mikrogramm/ml Injektionslösung	not available	7692.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Sufenta, injektionsvæske, opløsning	not available	13894	PIRAMAL CRITICAL CARE B.V.	DK
Sufentanil "Hameln"	DE/H/0275/003	55609	HAMELN PHARMA GMBH	DK
Sufentanil "Hameln"	DE/H/0275/003	55609	HAMELN PHARMA GMBH	DK

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
Sufentanil "HamelN"	DE/H/0275/003	55609	HAMELN PHARMA GMBH	DK
Sufentanil "HamelN"	DE/H/0275/003	55609	HAMELN PHARMA GMBH	DK
SUFENTANIL PIRAMAL 0,05 mg/ml soluzione iniettabile	not available	028347019	PIRAMAL CRITICAL CARE ITALIA SPA	IT
SUFENTANIL PIRAMAL 0,05 mg/ml soluzione iniettabile	not available	028347021	PIRAMAL CRITICAL CARE ITALIA SPA	IT
SUFENTANIL PIRAMAL 0,05 mg/ml soluzione iniettabile	not available	028347045	PIRAMAL CRITICAL CARE ITALIA SPA	IT
Sufentanil-hamelN 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696968	HAMELN PHARMA GMBH	PT
Sufentanil-hamelN 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696950	HAMELN PHARMA GMBH	PT
Sufentanil-hamelN 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696976	HAMELN PHARMA GMBH	PT
Sufentanil-hamelN 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696968	HAMELN PHARMA GMBH	PT
Sufentanil-hamelN 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696950	HAMELN PHARMA GMBH	PT
Sufentanil-hamelN 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696976	HAMELN PHARMA GMBH	PT
Sufentanil-hamelN 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696968	HAMELN PHARMA GMBH	PT
Sufentanil-hamelN 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696950	HAMELN PHARMA GMBH	PT
Sufentanil-hamelN 0,01	DE/H/0275/003	5696976	HAMELN PHARMA GMBH	PT

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
mg/ml solução injetável ou para perfusão				
Sufentanil-hameln 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696968	HAMELN PHARMA GMBH	PT
Sufentanil-hameln 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696950	HAMELN PHARMA GMBH	PT
Sufentanil-hameln 0,01 mg/ml solução injetável ou para perfusão	DE/H/0275/003	5696976	HAMELN PHARMA GMBH	PT
Sufentanil-hameln 10 microgram/ml, oplossing voor injectie/infusie	DE/H/0275/003	RVG 117066	HAMELN PHARMA GMBH	NL
Sufentanil-hameln 10 microgram/ml, oplossing voor injectie/infusie	DE/H/0275/003	RVG 117066	HAMELN PHARMA GMBH	NL
Sufentanil-hameln 10 microgram/ml, oplossing voor injectie/infusie	DE/H/0275/003	RVG 117066	HAMELN PHARMA GMBH	NL
Sufentanil-hameln 10 microgram/ml, oplossing voor injectie/infusie	DE/H/0275/003	RVG 117066	HAMELN PHARMA GMBH	NL
Sufentanil-hameln 10 Mikrogramm/ml Injektions-/Infusionslösung	DE/H/0275/003	137062	HAMELN PHARMA GMBH	AT
Sufentanil-hameln 10 Mikrogramm/ml Injektions-/Infusionslösung	DE/H/0275/003	137062	HAMELN PHARMA GMBH	AT
Sufentanil-hameln 10 Mikrogramm/ml Injektions-/Infusionslösung	DE/H/0275/003	137062	HAMELN PHARMA GMBH	AT
Sufentanil-hameln 10	DE/H/0275/003	137062	HAMELN PHARMA GMBH	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
Mikrogramm/ml Injektions- /Infusionslösung				
Sufentanil-hameln 10 Mikrogramm/ml Injektions- /Infusionslösung	DE/H/0275/003	94564.00.00	HAMELN PHARMA GMBH	DE
Sufentanil-hameln 10 Mikrogramm/ml Injektions- /Infusionslösung	DE/H/0275/003	94564.00.00	HAMELN PHARMA GMBH	DE
Sufentanil-hameln 10 Mikrogramm/ml Injektions- /Infusionslösung	DE/H/0275/003	94564.00.00	HAMELN PHARMA GMBH	DE
Sufentanil-hameln 10 Mikrogramm/ml Injektions- /Infusionslösung	DE/H/0275/003	94564.00.00	HAMELN PHARMA GMBH	DE