



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2022
EMA/137844/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: remifentanil

Procedure no.: PSUSA/00002617/202105



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
Ultiva 1 mg κόνις για παρασκευή πυκνού διαλύματος για παρασκευή ενέσιμου διαλύματος/διαλύματος προς έγχυση.	DE/H/0106/001	2327001	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Ultiva 2 mg κόνις για παρασκευή πυκνού διαλύματος για παρασκευή ενέσιμου διαλύματος/διαλύματος προς έγχυση.	DE/H/0106/002	2327002	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Ultiva 5 mg κόνις για παρασκευή πυκνού διαλύματος για παρασκευή ενέσιμου διαλύματος/διαλύματος προς έγχυση.	DE/H/0106/003	2327003	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Ultiva (remifentanil hydrochloride) for Injection 1 mg	not available	PL 39699/0095	ASPEN PHARMA TRADING LIMITED	XI
Ultiva (remifentanil hydrochloride) for Injection 2 mg	not available	PL 39699/0096	ASPEN PHARMA TRADING LIMITED	XI
Ultiva (remifentanil hydrochloride) for Injection 5 mg	not available	PL 39699/0097	ASPEN PHARMA TRADING LIMITED	XI

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
Ultiva 1 mg kuiva-aine välikonsentraatiksi injektio-/infuusionestettä varten, liuos	DE/H/0106/001	12408	ASPEN PHARMA TRADING LIMITED	FI
Ultiva 1 mg milteliai injekciniam ar infuziniam tirpalui	not available	LT/1/97/2229/001	ASPEN PHARMA TRADING LIMITED	LT
Ultiva 1 mg pó para concentrado para solução injetável/perfusão	DE-H-0106	2500189	ASPEN PHARMA TRADING LIMITED	PT
Ultiva 1 mg poeder voor concentraat voor oplossing voor injectie / infusie	DE/H/0106/001	BE181937	ASPEN PHARMA TRADING LIMITED	BE
ULTIVA 1 mg polvere per concentrato per soluzione iniettabile/infusione	DE/H/0106/001	033003017	ASPEN PHARMA TRADING LIMITED	IT
Ultiva 1 mg polvo para concentrado para solución inyectable y para perfusión.	DE/H/0106/001	61.488	ASPEN PHARMA TRADING LIMITED	ES
Ultiva 1 mg poudre pour solution à diluer injectable/ pour perfusion	DE/H/0106/001	2008019609	ASPEN PHARMA TRADING LIMITED	LU
Ultiva 1 mg poudre pour solution à diluer pour solution injectable/pour perfusion	DE/H/0106/001	BE181937	ASPEN PHARMA TRADING LIMITED	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
Ultiva 1 mg Powder for Concentrate for Solution for Infusion	not available	S01187	ASPEN PHARMA TRADING LIMITED	CY
Ultiva 1 mg Powder for Concentrate for Solution for Infusion	not available	PA 1691/032/001	ASPEN PHARMA TRADING LIMITED	IE
Ultiva 1 mg Powder for Concentrate for Solution for Infusion	not available	MA 955/01601	ASPEN PHARMA TRADING LIMITED	MT
Ultiva 1 mg prašek za raztopino za injiciranje ali infundiranje	not available	H/98/01579/001	ASPEN PHARMA TRADING LIMITED	SI
Ultiva 1 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- bzw. Infusionslösung Remifentanyl	DE/H/0106/001	36335.00.00	ASPEN PHARMA TRADING LIMITED	DE
Ultiva 1 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- /Infusionslösung	DE/H/0106/001	1-21677	ASPEN PHARMA TRADING LIMITED	AT
Ultiva 1 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- /Infusionslösung	DE/H/0106/001	BE181937	ASPEN PHARMA TRADING LIMITED	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
Ultiva 1 mg Pulver für ein Konzentrat zur Herstellung einer Injektions-/Infusionslösung	DE/H/0106/001	2008019609	ASPEN PHARMA TRADING LIMITED	LU
Ultiva 1 mg pulver til infusjonsvæske/injeksjons væske, oppløsning	not available	95-3195	ASPEN PHARMA TRADING LIMITED	NO
Ultiva 1 mg pulver til konzentrat til injektions- og infusionsvæske, opløsning	DE/H/0106/001	18289	ASPEN PHARMA TRADING LIMITED	DK
Ultiva 1 mg pulver till konzentrat till injektions-/infusionsvätska, lösning	DE/H/0106/001	12408	ASPEN PHARMA TRADING LIMITED	FI
Ultiva 1 mg pulver till konzentrat till injektions-/infusionsvätska, lösning.	not available	13767	ASPEN PHARMA TRADING LIMITED	SE
ULTIVA 1 mg, poudre pour solution injectable ou pour perfusion	DE/H/0106/001	34009 560 139 4 4	ASPEN PHARMA TRADING LIMITED	FR
Ultiva 2 mg kuiva-aine välikonsentraatiksi injektio-/infusionestettä varten, liuos	DE/H/0106/002	12409	ASPEN PHARMA TRADING LIMITED	FI
Ultiva 2 mg pó para concentrado para solução injetável/perfusão	DE-H-0106	2500288	ASPEN PHARMA TRADING LIMITED	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
Ultiva 2 mg poeder voor concentraat voor oplossing voor injectie / infusie	DE/H/0106/002	BE181912	ASPEN PHARMA TRADING LIMITED	BE
ULTIVA 2 mg polvere per concentrato per soluzione iniettabile/infusione	DE/H/0106/002	033003029	ASPEN PHARMA TRADING LIMITED	IT
Ultiva 2 mg polvo para concentrado para solución inyectable y para perfusión.	DE/H/0106/002	61.489	ASPEN PHARMA TRADING LIMITED	ES
Ultiva 2 mg poudre pour solution à diluer injectable/ pour perfusion	DE/H/0106/002	2008019610	ASPEN PHARMA TRADING LIMITED	LU
Ultiva 2 mg poudre pour solution à diluer pour solution injectable/pour perfusion	DE/H/0106/002	BE181912	ASPEN PHARMA TRADING LIMITED	BE
Ultiva 2 mg Powder for Concentrate for Solution for Infusion	not available	S01188	ASPEN PHARMA TRADING LIMITED	CY
Ultiva 2 mg Powder for Concentrate for Solution for Infusion	not available	PA 1691/032/002	ASPEN PHARMA TRADING LIMITED	IE
Ultiva 2 mg Powder for Concentrate for Solution for Infusion	not available	MA 955/01602	ASPEN PHARMA TRADING LIMITED	MT

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
Ultiva 2 mg prášok na injekčný/infúzny roztok	not available	05/0303/00-S	ASPEN PHARMA TRADING LIMITED	SK
Ultiva 2 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- bzw. Infusionslösung Remifentanyl	DE/H/0106/002	36335.01.00	ASPEN PHARMA TRADING LIMITED	DE
Ultiva 2 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- /Infusionslösung	DE/H/0106/002	1-21678	ASPEN PHARMA TRADING LIMITED	AT
Ultiva 2 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- /Infusionslösung	DE/H/0106/002	BE181912	ASPEN PHARMA TRADING LIMITED	BE
Ultiva 2 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- /Infusionslösung	DE/H/0106/002	2008019610	ASPEN PHARMA TRADING LIMITED	LU
Ultiva 2 mg pulver til infusjonsvæske/injeksjons væske, oppløsning	not available	13-9568	ASPEN PHARMA TRADING LIMITED	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
Ultiva 2 mg pulver til koncentrat til injektions- og infusionsvæske, opløsning	DE/H/0106/002	18290	ASPEN PHARMA TRADING LIMITED	DK
Ultiva 2 mg pulver till koncentrat till injektions-/infusionsvätska, lösning	DE/H/0106/002	12409	ASPEN PHARMA TRADING LIMITED	FI
Ultiva 2 mg pulver till koncentrat till injektions-/infusionsvätska, lösning	not available	13768	ASPEN PHARMA TRADING LIMITED	SE
ULTIVA 2 mg, poudre pour solution injectable ou pour perfusion	DE/H/0106/002	34009 560 140 2 6	ASPEN PHARMA TRADING LIMITED	FR
Ultiva 5 mg kuiva-aine välikonsentraatiksi injektio-/infusionestettä varten, liuos	DE/H/0106/003	12410	ASPEN PHARMA TRADING LIMITED	FI
Ultiva 5 mg pó para concentrado para solução injetável/perfusão	DE-H-0106	2500387	ASPEN PHARMA TRADING LIMITED	PT
Ultiva 5 mg poeder voor concentraat voor oplossing voor injectie / infusie	DE/H/0106/003	BE181921	ASPEN PHARMA TRADING LIMITED	BE
ULTIVA 5 mg polvere per concentrato per soluzione iniettabile/infusione	DE/H/0106/003	033003031	ASPEN PHARMA TRADING LIMITED	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
Ultiva 5 mg polvo para concentrado para solución inyectable y para perfusión.	DE/H/0106/003	61.490	ASPEN PHARMA TRADING LIMITED	ES
Ultiva 5 mg poudre pour solution à diluer injectable/ pour perfusion	DE/H/0106/003	2008019611	ASPEN PHARMA TRADING LIMITED	LU
Ultiva 5 mg poudre pour solution à diluer pour solution injectable/pour perfusion	DE/H/0106/003	BE181921	ASPEN PHARMA TRADING LIMITED	BE
Ultiva 5 mg Powder for Concentrate for Solution for Infusion	not available	S01189	ASPEN PHARMA TRADING LIMITED	CY
Ultiva 5 mg Powder for Concentrate for Solution for Infusion	not available	PA 1691/032/003	ASPEN PHARMA TRADING LIMITED	IE
Ultiva 5 mg Powder for Concentrate for Solution for Infusion	not available	MA 955/01603	ASPEN PHARMA TRADING LIMITED	MT
Ultiva 5 mg prašek za raztopino za injiciranje ali infundiranje	not available	H/98/01579/002	ASPEN PHARMA TRADING LIMITED	SI
Ultiva 5 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- bzw. Infusionslösung Remifentanyl	DE/H/0106/003	36335.02.00	ASPEN PHARMA TRADING LIMITED	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
Ultiva 5 mg Pulver für ein Konzentrat zur Herstellung einer Injektions-/Infusionslösung	DE/H/0106/003	1-21679	ASPEN PHARMA TRADING LIMITED	AT
Ultiva 5 mg Pulver für ein Konzentrat zur Herstellung einer Injektions-/Infusionslösung	DE/H/0106/003	BE181921	ASPEN PHARMA TRADING LIMITED	BE
Ultiva 5 mg Pulver für ein Konzentrat zur Herstellung einer Injektions-/Infusionslösung	DE/H/0106/003	2008019611	ASPEN PHARMA TRADING LIMITED	LU
Ultiva 5 mg pulver til infusjonsvæske/injeksjons væske, oppløsning	not available	13-9567	ASPEN PHARMA TRADING LIMITED	NO
Ultiva 5 mg pulver til konzentrat til injektions- og infusionsvæske, opløsning	DE/H/0106/003	18291	ASPEN PHARMA TRADING LIMITED	DK
Ultiva 5 mg pulver till konzentrat till injektions-/infusionsvätska, lösning	DE/H/0106/003	12410	ASPEN PHARMA TRADING LIMITED	FI
Ultiva 5 mg pulver till konzentrat till injektions-/infusionsvätska, lösning	not available	13769	ASPEN PHARMA TRADING LIMITED	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
ULTIVA 5 mg, poudre pour solution injectable ou pour perfusion	DE/H/0106/003	34009 560 164 9 5	ASPEN PHARMA TRADING LIMITED	FR
Ultiva, 1 mg poeder voor concentraat voor oplossing voor injectie/infusie	DE/H/0106/001	RVG 20601	ASPEN PHARMA TRADING LIMITED	NL
Ultiva, 1 mg, proszek do sporządzania roztworu do wstrzykiwań i infuzji	not available	4580	ASPEN PHARMA TRADING LIMITED	PL
Ultiva, 2 mg poeder voor concentraat voor oplossing voor injectie/infusie	DE/H/0106/002	RVG 20602	ASPEN PHARMA TRADING LIMITED	NL
Ultiva, 2 mg, proszek do sporządzania roztworu do wstrzykiwań i infuzji	not available	4581	ASPEN PHARMA TRADING LIMITED	PL
Ultiva, 5 mg poeder voor concentraat voor oplossing voor injectie/infusie	DE/H/0106/003	RVG 20603	ASPEN PHARMA TRADING LIMITED	NL
Ultiva, 5 mg, proszek do sporządzania roztworu do wstrzykiwań i infuzji	not available	4582	ASPEN PHARMA TRADING LIMITED	PL