



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2022
EMA/37490/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): fentanyl (transdermal patches, solution for injection - nationally authorised product only)

Procedure no.: PSUSA/00001370/202204



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
Durogesic	NL/H/3915/005	15454	JANSSEN-CILAG A/S	DK
Durogesic	NL/H/3915/002	15451	JANSSEN-CILAG A/S	DK
Durogesic	NL/H/3915/003	15452	JANSSEN-CILAG A/S	DK
Durogesic	NL/H/3915/001	37604	JANSSEN-CILAG A/S	DK
Durogesic	NL/H/3915/004	15453	JANSSEN-CILAG A/S	DK
DUROGESIC 100 microgram/uur pleister voor transdermaal gebruik	NL/H/3915/005	BE177834	JANSSEN-CILAG NV	BE
Durogesic 100 microgramas/hora sistema transdérmico	NL/H/3915/005	2505584	JANSSEN FARMACÉUTICA PORTUGAL, LDA	PT
DUROGESIC 100 microgrammes/heure, dispositif transdermique	NL/H/3915/005	BE177834	JANSSEN-CILAG NV	BE
DUROGESIC 100 microgrammes/heure, dispositif transdermique	NL/H/3915/005	34009 342 387 6 5	JANSSEN-CILAG	FR
DUROGESIC 100 microgrammes/heure, dispositif transdermique	NL/H/3915/005	2008059775	JANSSEN-CILAG NV	LU
DUROGESIC 100 microgrammi/ora cerotto transdermico	NL/H/3915/005	029212089	JANSSEN-CILAG SPA	IT
DUROGESIC 100 microgrammi/ora cerotto transdermico	NL/H/3915/005	029212382	JANSSEN-CILAG SPA	IT
DUROGESIC 100 microgrammi/ora cerotto transdermico	NL/H/3915/005	029212394	JANSSEN-CILAG SPA	IT
DUROGESIC 100 microgrammi/ora cerotto transdermico	NL/H/3915/005	029212406	JANSSEN-CILAG SPA	IT
DUROGESIC 100 microgrammi/ora cerotto	NL/H/3915/005	029212418	JANSSEN-CILAG SPA	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
transdermico				
DUROGESIC 100 microgrammi/ora cerotto transdermico	NL/H/3915/005	029212420	JANSSEN-CILAG SPA	IT
DUROGESIC 100 microgrammi/ora cerotto transdermico	NL/H/3915/005	029212432	JANSSEN-CILAG SPA	IT
DUROGESIC 100 microgrammi/ora cerotto transdermico	NL/H/3915/005	029212444	JANSSEN-CILAG SPA	IT
DUROGESIC 100 míkróg/klst. forðaplástur	NL/H/3915/005	MTNR 930069 (IS)	JANSSEN-CILAG AB	IS
Durogesic 100 mikrog/time depotplaster	NL/H/3915/005	8100	JANSSEN-CILAG A/S	NO
Durogesic 100 mikrog/timme depotplåster	NL/H/3915/005	11794	JANSSEN-CILAG OY	FI
Durogesic 100 mikrog/tunti depotlaastari	NL/H/3915/005	11794	JANSSEN-CILAG OY	FI
Durogesic 100 mikrogram/timme depotplåster	NL/H/3915/005	12486	JANSSEN-CILAG AB	SE
DUROGESIC 100 mikrograma/sat transdermalni flaster	NL/H/3915/005	HR-H-826093753	JOHNSON & JOHNSON S.E. D.O.O.	HR
DUROGESIC 100 mikrogramm/óra transzdermális tapasz	NL/H/3915/005	OGYI-T-4530/04	JANSSEN-CILAG KFT.	HU
DUROGESIC 100 mikrogramm/óra transzdermális tapasz	NL/H/3915/005	OGYI-T-4530/10	JANSSEN-CILAG KFT.	HU
Durogesic 100 Mikrogramm/Stunde - Transdermales Pflaster	NL/H/3915/005	1-21366	JANSSEN-CILAG PHARMA GMBH	AT
DUROGESIC 100 Mikrogramm/Stunde	NL/H/3915/005	BE177834	JANSSEN-CILAG NV	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
Transdermales Pflaster				
DUROGESIC 100 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/005	2008059775	JANSSEN-CILAG NV	LU
DUROGESIC 100 mikrogramov/h transdermalni obliž	NL/H/3915/005	H/00/00516/005	JOHNSON & JOHNSON D.O.O.	SI
DUROGESIC 100 mikrogramů/hodinu transdermální náplast	NL/H/3915/005	65/719/97-C	JANSSEN-CILAG S.R.O	CZ
DUROGESIC 100 µg/uur, pleisters voor transdermaal gebruik	NL/H/3915/005	RVG 16848	JANSSEN-CILAG BV	NL
DUROGESIC 100 μικρογραμμάρια/ώρα διαδερμικό έμπλαστρο	NL/H/3915/005	39754/08.04.2019	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
DUROGESIC 100 μικρογραμμάρια/ώρα διαδερμικό επίθεμα	NL/H/3915/005	17987	JANSSEN-CILAG INTERNATIONAL NV	CY
DUROGESIC 12 microgram/uur pleister voor transdermaal gebruik	NL/H/3915/001	BE274181	JANSSEN-CILAG NV	BE
Durogesic 12 microgramas/hora sistema transdérmico	NL/H/3915/001	5738398	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
DUROGESIC 12 microgrammes/heure, dispositif transdermique	NL/H/3915/001	BE274181	JANSSEN-CILAG NV	BE
DUROGESIC 12 microgrammes/heure, dispositif transdermique	NL/H/3915/001	34009 369 851 5 5	JANSSEN-CILAG	FR
DUROGESIC 12 microgrammes/heure, dispositif transdermique	NL/H/3915/001	2008059771	JANSSEN-CILAG NV	LU
DUROGESIC 12 microgrammi/ora cerotto transdermico	NL/H/3915/001	029212139	JANSSEN-CILAG SPA	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
DUROGESIC 12 microgrammi/ora cerotto transdermico	NL/H/3915/001	029212091	JANSSEN-CILAG SPA	IT
DUROGESIC 12 microgrammi/ora cerotto transdermico	NL/H/3915/001	029212103	JANSSEN-CILAG SPA	IT
DUROGESIC 12 microgrammi/ora cerotto transdermico	NL/H/3915/001	029212115	JANSSEN-CILAG SPA	IT
DUROGESIC 12 microgrammi/ora cerotto transdermico	NL/H/3915/001	029212127	JANSSEN-CILAG SPA	IT
DUROGESIC 12 microgrammi/ora cerotto transdermico	NL/H/3915/001	029212141	JANSSEN-CILAG SPA	IT
DUROGESIC 12 microgrammi/ora cerotto transdermico	NL/H/3915/001	029212154	JANSSEN-CILAG SPA	IT
DUROGESIC 12 microgrammi/ora cerotto transdermico	NL/H/3915/001	029212166	JANSSEN-CILAG SPA	IT
DUROGESIC 12 míkróg/klst. forðaplástur	NL/H/3915/001	IS/1/05/107/01	JANSSEN-CILAG AB	IS
Durogesic 12 mikrog/time depotplaster	NL/H/3915/001	04-2767	JANSSEN-CILAG A/S	NO
Durogesic 12 mikrog/timme depotplåster	NL/H/3915/001	19678	JANSSEN-CILAG OY	FI
Durogesic 12 mikrog/tunti depotlaastari	NL/H/3915/001	19678	JANSSEN-CILAG OY	FI
Durogesic 12 mikrogram/timme depotplåster	NL/H/3915/001	21308	JANSSEN-CILAG AB	SE
DUROGESIC 12 mikrograma/sat transdermalni flaster	NL/H/3915/001	HR-H-516334089	JOHNSON & JOHNSON S.E. D.O.O.	HR

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
DUROGESIC 12 mikrogramm/óra transzdermális tapasz	NL/H/3915/001	OGYI-T-4530/05	JANSSEN-CILAG KFT.	HU
DUROGESIC 12 mikrogramm/óra transzdermális tapasz	NL/H/3915/001	OGYI-T-4530/06	JANSSEN-CILAG KFT.	HU
Durogesic 12 Mikrogramm/Stunde - Transdermales Pflaster	NL/H/3915/001	1-26080	JANSSEN-CILAG PHARMA GMBH	AT
DUROGESIC 12 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/001	BE274181	JANSSEN-CILAG NV	BE
DUROGESIC 12 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/001	2008059771	JANSSEN-CILAG NV	LU
DUROGESIC 12 mikrogramov/h transdermalni obliž	NL/H/3915/001	H/00/00516/001	JOHNSON & JOHNSON D.O.O.	SI
DUROGESIC 12 mikrogramů/hodinu transdermální náplast	NL/H/3915/001	65/059/06-C	JANSSEN-CILAG S.R.O	CZ
DUROGESIC 12 µg/uur, pleisters voor transdermaal gebruik	NL/H/3915/001	RVG 31418	JANSSEN-CILAG BV	NL
DUROGESIC 12 μικρογραμμάρια/ώρα διαδερμικό έμπλαστρο	NL/H/3915/001	39755/08.04.2019	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
DUROGESIC 25 microgram/uur pleister voor transdermaal gebruik	NL/H/3915/002	BE177904	JANSSEN-CILAG NV	BE
Durogesic 25 microgramas/hora sistema transdémico	NL/H/3915/002	2505287	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
DUROGESIC 25 microgrammes/heure, dispositif transdermique	NL/H/3915/002	BE177904	JANSSEN-CILAG NV	BE
DUROGESIC 25	NL/H/3915/002	34009 342 383 0 7	JANSSEN-CILAG	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
microgrammes/heure, dispositif transdermique				
DUROGESIC 25 microgrammes/heure, dispositif transdermique	NL/H/3915/002	2008059772	JANSSEN-CILAG NV	LU
DUROGESIC 25 microgrammi/ora cerotto transdermico	NL/H/3915/002	029212053	JANSSEN-CILAG SPA	IT
DUROGESIC 25 microgrammi/ora cerotto transdermico	NL/H/3915/002	029212178	JANSSEN-CILAG SPA	IT
DUROGESIC 25 microgrammi/ora cerotto transdermico	NL/H/3915/002	029212180	JANSSEN-CILAG SPA	IT
DUROGESIC 25 microgrammi/ora cerotto transdermico	NL/H/3915/002	029212192	JANSSEN-CILAG SPA	IT
DUROGESIC 25 microgrammi/ora cerotto transdermico	NL/H/3915/002	029212204	JANSSEN-CILAG SPA	IT
DUROGESIC 25 microgrammi/ora cerotto transdermico	NL/H/3915/002	029212216	JANSSEN-CILAG SPA	IT
DUROGESIC 25 microgrammi/ora cerotto transdermico	NL/H/3915/002	029212228	JANSSEN-CILAG SPA	IT
DUROGESIC 25 microgrammi/ora cerotto transdermico	NL/H/3915/002	029212230	JANSSEN-CILAG SPA	IT
DUROGESIC 25 míkroóg/klst. forðaplástur	NL/H/3915/002	MTNR 930066 (IS)	JANSSEN-CILAG AB	IS
DUROGESIC 25 mikrog/time depotplaster	NL/H/3915/002	8097	JANSSEN-CILAG A/S	NO
Durogesic 25 mikrog/timme depotplåster	NL/H/3915/002	11791	JANSSEN-CILAG OY	FI
Durogesic 25	NL/H/3915/002	11791	JANSSEN-CILAG OY	FI

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mikrog/tunti depotlaastari				
Durogesic 25 mikrogram/timme depotplåster	NL/H/3915/002	12483	JANSSEN-CILAG AB	SE
DUROGESIC 25 mikrograma/sat transdermalni flaster	NL/H/3915/002	HR-H-222344953	JOHNSON & JOHNSON S.E. D.O.O.	HR
DUROGESIC 25 mikrogramm/óra transzdermális tapasz	NL/H/3915/002	OGYI-T-4530/01	JANSSEN-CILAG KFT.	HU
DUROGESIC 25 mikrogramm/óra transzdermális tapasz	NL/H/3915/002	OGYI-T-4530/07	JANSSEN-CILAG KFT.	HU
Durogesic 25 Mikrogramm/Stunde - Transdermales Pflaster	NL/H/3915/002	1-21367	JANSSEN-CILAG PHARMA GMBH	AT
DUROGESIC 25 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/002	BE177904	JANSSEN-CILAG NV	BE
DUROGESIC 25 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/002	2008059772	JANSSEN-CILAG NV	LU
DUROGESIC 25 mikrogramov/h transdermalni obliž	NL/H/3915/002	H/00/00516/002	JOHNSON & JOHNSON D.O.O.	SI
DUROGESIC 25 mikrogramů/hodinu transdermální náplast	NL/H/3915/002	65/716/97-C	JANSSEN-CILAG S.R.O	CZ
DUROGESIC 25 µg/uur, pleisters voor transdermaal gebruik	NL/H/3915/002	RVG 16845	JANSSEN-CILAG BV	NL
DUROGESIC 25 μικρογραμμάρια/ώρα διαδερμικό έμπλαστρο	NL/H/3915/002	83556/17/08.04.2019	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
DUROGESIC 25 μικρογραμμάρια/ώρα διαδερμικό επίθεμα	NL/H/3915/002	17985	JANSSEN-CILAG INTERNATIONAL NV	CY

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
DUROGESIC 50 microgram/uur pleister voor transdermaal gebruik	NL/H/3915/003	BE177886	JANSSEN-CILAG NV	BE
Durogesic 50 microgramas/hora sistema transdémico	NL/H/3915/003	2505386	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
DUROGESIC 50 microgrammes/heure, dispositif transdermique	NL/H/3915/003	BE177886	JANSSEN-CILAG NV	BE
DUROGESIC 50 microgrammes/heure, dispositif transdermique	NL/H/3915/003	34009 342 384 7 5	JANSSEN-CILAG	FR
DUROGESIC 50 microgrammes/heure, dispositif transdermique	NL/H/3915/003	2008059773	JANSSEN-CILAG NV	LU
DUROGESIC 50 microgrammi/ora cerotto transdermico	NL/H/3915/003	029212065	JANSSEN-CILAG SPA	IT
DUROGESIC 50 microgrammi/ora cerotto transdermico	NL/H/3915/003	029212242	JANSSEN-CILAG SPA	IT
DUROGESIC 50 microgrammi/ora cerotto transdermico	NL/H/3915/003	029212255	JANSSEN-CILAG SPA	IT
DUROGESIC 50 microgrammi/ora cerotto transdermico	NL/H/3915/003	029212267	JANSSEN-CILAG SPA	IT
DUROGESIC 50 microgrammi/ora cerotto transdermico	NL/H/3915/003	029212279	JANSSEN-CILAG SPA	IT
DUROGESIC 50 microgrammi/ora cerotto transdermico	NL/H/3915/003	029212281	JANSSEN-CILAG SPA	IT
DUROGESIC 50 microgrammi/ora cerotto transdermico	NL/H/3915/003	029212293	JANSSEN-CILAG SPA	IT
DUROGESIC 50	NL/H/3915/003	029212305	JANSSEN-CILAG SPA	IT

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microgrammi/ora cerotto transdermico				
DUROGESIC 50 míkróg/klst. forðaplástur	NL/H/3915/003	MTNR 930067 (IS)	JANSSEN-CILAG AB	IS
Durogesic 50 mikrog/time depotplaster	NL/H/3915/003	8098	JANSSEN-CILAG A/S	NO
Durogesic 50 mikrog/timme depotplåster	NL/H/3915/003	11792	JANSSEN-CILAG OY	FI
Durogesic 50 mikrog/tunti depotlaastari	NL/H/3915/003	11792	JANSSEN-CILAG OY	FI
Durogesic 50 mikrogram/timme depotplåster	NL/H/3915/003	12484	JANSSEN-CILAG AB	SE
DUROGESIC 50 mikrograma/sat transdermalni flaster	NL/H/3915/003	HR-H-239768718	JOHNSON & JOHNSON S.E. D.O.O.	HR
DUROGESIC 50 mikrogramm/óra transzdermális tapasz	NL/H/3915/003	OGYI-T-4530/02	JANSSEN-CILAG KFT.	HU
DUROGESIC 50 mikrogramm/óra transzdermális tapasz	NL/H/3915/003	OGYI-T-4530/08	JANSSEN-CILAG KFT.	HU
Durogesic 50 Mikrogramm/Stunde - Transdermales Pflaster	NL/H/3915/003	1-21376	JANSSEN-CILAG PHARMA GMBH	AT
DUROGESIC 50 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/003	BE177886	JANSSEN-CILAG NV	BE
DUROGESIC 50 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/003	2008059773	JANSSEN-CILAG NV	LU
DUROGESIC 50 mikrogramov/h transdermalni obliž	NL/H/3915/003	H/00/00516/003	JOHNSON & JOHNSON D.O.O.	SI
DUROGESIC 50	NL/H/3915/003	65/717/97-C	JANSSEN-CILAG S.R.O	CZ

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mikrogramű/hodinu transdermální náplast				
DUROGESIC 50 µg/uur, pleisters voor transdermaal gebruik	NL/H/3915/003	RVG 16846	JANSSEN-CILAG BV	NL
DUROGESIC 50 μικρογραμμάρια/ώρα διαδερμικό έμπλαστρο	NL/H/3915/003	39752/08.04.2019	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
DUROGESIC 50 μικρογραμμάρια/ώρα διαδερμικό επίθεμα	NL/H/3915/003	17986	JANSSEN-CILAG INTERNATIONAL NV	CY
DUROGESIC 75 microgram/uur pleister voor transdermaal gebruik	NL/H/3915/004	BE177895	JANSSEN-CILAG NV	BE
Durogesic 75 microgramas/hora sistema transdérnico	NL/H/3915/004	2505485	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
DUROGESIC 75 microgrammes/heure, dispositif transdermique	NL/H/3915/004	BE177895	JANSSEN-CILAG NV	BE
DUROGESIC 75 microgrammes/heure, dispositif transdermique	NL/H/3915/004	34009 342 385 3 6	JANSSEN-CILAG	FR
DUROGESIC 75 microgrammes/heure, dispositif transdermique	NL/H/3915/004	2008059774	JANSSEN-CILAG NV	LU
DUROGESIC 75 microgrammi/ora cerotto transdermico	NL/H/3915/004	029212077	JANSSEN-CILAG SPA	IT
DUROGESIC 75 microgrammi/ora cerotto transdermico	NL/H/3915/004	029212317	JANSSEN-CILAG SPA	IT
DUROGESIC 75 microgrammi/ora cerotto transdermico	NL/H/3915/004	029212329	JANSSEN-CILAG SPA	IT
DUROGESIC 75 microgrammi/ora cerotto	NL/H/3915/004	029212331	JANSSEN-CILAG SPA	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
transdermico				
DUROGESIC 75 microgrammi/ora cerotto transdermico	NL/H/3915/004	029212343	JANSSEN-CILAG SPA	IT
DUROGESIC 75 microgrammi/ora cerotto transdermico	NL/H/3915/004	029212356	JANSSEN-CILAG SPA	IT
DUROGESIC 75 microgrammi/ora cerotto transdermico	NL/H/3915/004	029212368	JANSSEN-CILAG SPA	IT
DUROGESIC 75 microgrammi/ora cerotto transdermico	NL/H/3915/004	029212370	JANSSEN-CILAG SPA	IT
DUROGESIC 75 mÍkróg/klst. forðaplástur	NL/H/3915/004	MTNR 930068 (IS)	JANSSEN-CILAG AB	IS
Durogesic 75 mikrog/time depotplaster	NL/H/3915/004	8099	JANSSEN-CILAG A/S	NO
Durogesic 75 mikrog/timme depotplåster	NL/H/3915/004	11793	JANSSEN-CILAG OY	FI
Durogesic 75 mikrog/tunti depotlaastari	NL/H/3915/004	11793	JANSSEN-CILAG OY	FI
Durogesic 75 mikrogram/timme depotplåster	NL/H/3915/004	12485	JANSSEN-CILAG AB	SE
DUROGESIC 75 mikrograma/sat transdermalni flaster	NL/H/3915/004	HR-H-613618293	JOHNSON & JOHNSON S.E. D.O.O.	HR
DUROGESIC 75 mikrogramm/óra transzdermális tapasz	NL/H/3915/004	OGYI-T-4530/03	JANSSEN-CILAG KFT.	HU
DUROGESIC 75 mikrogramm/óra transzdermális tapasz	NL/H/3915/004	OGYI-T-4530/09	JANSSEN-CILAG KFT.	HU
Durogesic 75 Mikrogramm/Stunde -	NL/H/3915/004	1-21365	JANSSEN-CILAG 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
Transdermales Pflaster				
DUROGESIC 75 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/004	BE177895	JANSSEN-CILAG NV	BE
DUROGESIC 75 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/004	2008059774	JANSSEN-CILAG NV	LU
DUROGESIC 75 mikrogramov/h transdermalni obliž	NL/H/3915/004	H/00/00516/004	JOHNSON & JOHNSON D.O.O.	SI
DUROGESIC 75 mikrogramů/hodinu transdermální náplast	NL/H/3915/004	65/718/97-C	JANSSEN-CILAG S.R.O	CZ
DUROGESIC 75 µg/uur, pleisters voor transdermaal gebruik	NL/H/3915/004	RVG 16847	JANSSEN-CILAG BV	NL
DUROGESIC 75 μικρογραμμάρια/ώρα διαδερμικό έμπλαστρο	NL/H/3915/004	39753/08.04.2019	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
Durogesic Matrix 100 microgramos/hora parches transdérmicos	NL/H/3915/005	61.961	JANSSEN-CILAG S.A.	ES
Durogesic Matrix 12 microgramos/hora parches transdérmicos	NL/H/3915/001	67.029	JANSSEN-CILAG S.A.	ES
Durogesic Matrix 25 microgramos/hora parches transdérmicos	NL/H/3915/002	61.959	JANSSEN-CILAG S.A.	ES
Durogesic Matrix 50 microgramos/hora parches transdérmicos	NL/H/3915/003	61.960	JANSSEN-CILAG S.A.	ES
Durogesic Matrix 75 microgramos/hora parches transdérmicos	NL/H/3915/004	65.032	JANSSEN-CILAG S.A.	ES
Durogesic SMAT 100 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/005	18411.03.00	JANSSEN-CILAG GMBH	DE
Durogesic SMAT 12	NL/H/3915/001	60415.00.00	JANSSEN-CILAG 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
Mikrogramm/Stunde Transdermales Pflaster				
Durogesic SMAT 25 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/002	18411.00.00	JANSSEN-CILAG GMBH	DE
Durogesic SMAT 50 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/003	18411.01.00	JANSSEN-CILAG GMBH	DE
Durogesic SMAT 75 Mikrogramm/Stunde Transdermales Pflaster	NL/H/3915/004	18411.02.00	JANSSEN-CILAG GMBH	DE
Durogesic, 100 µg/h, system transdermalny, plaster	NL/H/3915/005	7657	JANSSEN-CILAG INTERNATIONAL NV	PL
Durogesic, 12 µg/h, system transdermalny, plaster	NL/H/3915/001	12949	JANSSEN-CILAG INTERNATIONAL NV	PL
Durogesic, 25 µg/h, system transdermalny, plaster	NL/H/3915/002	7654	JANSSEN-CILAG INTERNATIONAL NV	PL
Durogesic, 50 µg/h, system transdermalny, plaster	NL/H/3915/003	7655	JANSSEN-CILAG INTERNATIONAL NV	PL
Durogesic, 75 µg/h, system transdermalny, plaster	NL/H/3915/004	7656	JANSSEN-CILAG INTERNATIONAL NV	PL
Durogesic® DTrans® 100 micrograms/hour transdermal patch	NL/H/3915/005	PA 22612/004/004	JANSSEN SCIENCES IRELAND UC	IE
Durogesic® DTrans® 100 micrograms/hour transdermal patch	NL/H/3915/005	PL 00242/0195	JANSSEN-CILAG LIMITED	XI
Durogesic® DTrans® 12 micrograms/hour transdermal patch	NL/H/3915/001	PA 22612/004/005	JANSSEN SCIENCES IRELAND UC	IE
Durogesic® DTrans® 12 micrograms/hour transdermal patch	NL/H/3915/001	PL 00242/0409	JANSSEN-CILAG 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
Durogesic® DTrans® 25 micrograms/hour transdermal patch	NL/H/3915/002	PA 22612/004/001	JANSSEN SCIENCES IRELAND UC	IE
Durogesic® DTrans® 25 micrograms/hour transdermal patch	NL/H/3915/002	PL 00242/0192	JANSSEN-CILAG LIMITED	XI
Durogesic® DTrans® 50 micrograms/hour transdermal patch	NL/H/3915/003	PA 22612/004/002	JANSSEN SCIENCES IRELAND UC	IE
Durogesic® DTrans® 50 micrograms/hour transdermal patch	NL/H/3915/003	PL 00242/0193	JANSSEN-CILAG LIMITED	XI
Durogesic® DTrans® 75 micrograms/hour transdermal patch	NL/H/3915/004	PA 22612/004/003	JANSSEN SCIENCES IRELAND UC	IE
Durogesic® DTrans® 75 micrograms/hour transdermal patch	NL/H/3915/004	PL 00242/0194	JANSSEN-CILAG LIMITED	XI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/025	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/026	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/027	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/028	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/029	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/030	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h	DE/H/1147/003	H/09/00883/031	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI

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
transdermalni obliži				
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/032	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/033	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/034	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/035	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Epufen 37,5 mikrogramov/h transdermalni obliži	DE/H/1147/003	H/09/00883/036	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Fentalis 12,5 mikrogramů/hodinu transdermální náplast	DE/H/0765/001	65/417/07-C	SANDOZ S.R.O.	CZ
FentaMat Sandoz 37,5 Mikrogramm/h Transdermales Pflaster	DE/H/1147/003	69440.00.00	HEXAL AG	DE
FENTANEST 0,1 mg/2ml soluzione iniettabile Fentanil.	not available	020473029	PIRAMAL CRITICAL CARE ITALIA SPA	IT
Fentanest 0,05 mg/ml solução injectável	not available	3129681	PIRAMAL CRITICAL CARE B.V.	PT
Fentanest 0,05 mg/ml solução injectável	not available	3283983	PIRAMAL CRITICAL CARE B.V.	PT
Fentanest 0,05 mg/ml solução injectável	not available	8176339	PIRAMAL CRITICAL CARE B.V.	PT
Fentanest 0,05 mg/ml solução injectável	not available	8176321	PIRAMAL CRITICAL CARE B.V.	PT
Fentanyl - 1 A Pharma 150 µg/h Matrixpflaster, transdermales Pflaster	not available	69837.00.00	1 A PHARMA GMBH	DE
Fentanyl - 1 A Pharma 37,5 µg/h Matrixpflaster,	not available	67846.00.00	1 A PHARMA GMBH	DE

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transdermales Pflaster				
Fentanyl - 1 A Pharma Matrixpflaster 150 µg/h, transdermales Pflaster	DE/H/1048/002	68480.00.00	1 A PHARMA GMBH	DE
Fentanyl - 1 A Pharma Matrixpflaster 150 µg/h, transdermales Pflaster	DE/H/1048/002	68480.00.00	1 A PHARMA GMBH	DE
Fentanyl - 1 A Pharma Matrixpflaster 37,5 µg/h, transdermales Pflaster	DE/H/1048/001	68567.00.00	1 A PHARMA GMBH	DE
Fentanyl - 1 A Pharma Matrixpflaster 37,5 µg/h, transdermales Pflaster	DE/H/1048/001	68567.00.00	1 A PHARMA GMBH	DE
Fentanyl 1A Pharma 150 Mikrogramm/h - transdermales Matrixpflaster	DE/H/1048/002	1-27662	1A PHARMA GMBH	AT
Fentanyl 1A Pharma 150 Mikrogramm/h - transdermales Matrixpflaster	DE/H/1048/002	1-27662	1A PHARMA GMBH	AT
Fentanyl 1A Pharma 37,5 Mikrogramm/h - transdermales Matrixpflaster	DE/H/1048/001	1-27661	1A PHARMA GMBH	AT
Fentanyl 1A Pharma 37,5 Mikrogramm/h - transdermales Matrixpflaster	DE/H/1048/001	1-27661	1A PHARMA GMBH	AT
Fentanyl 50 mikrog/ml injektioneste, liuos	not available	933	PIRAMAL CRITICAL CARE B.V.	FI
FENTANYL 50 mikrograma/ml otopina za injekciju	not available	HR-H-978290024	PIRAMAL CRITICAL CARE B.V.	HR
Fentanyl Hexal 150 Mikrogramm/h - transdermales Matrixpflaster	DE/H/1047/002	1-27664	HEXAL 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
Fentanyl Hexal 37,5 Mikrogramm/h - transdermales Matrixpflaster	DE/H/1047/001	1-27663	HEXAL PHARMA GMBH	AT
FENTANYL PIRAMAL 0,05 mg/ml injekční roztok	not available	90/218/70-C	PIRAMAL CRITICAL CARE B.V.	CZ
FENTANYL PIRAMAL 100 microgrammes/2 ml, solution injectable en ampoule	not available	34009 558 783 7 7	PIRAMAL CRITICAL CARE B.V.	FR
FENTANYL PIRAMAL 500 microgrammes/10 ml, solution injectable en ampoule	not available	34009 558 784 3 8	PIRAMAL CRITICAL CARE B.V.	FR
FENTANYL PIRAMAL 500 microgrammes/10 ml, solution injectable en ampoule	not available	34009 556 137 0 1	PIRAMAL CRITICAL CARE B.V.	FR
Fentanyl Sandoz 150 µg/h Transdermales Pflaster	DE/H/1049/002	68583.00.00	HEXAL AG	DE
Fentanyl Sandoz 37,5 µg/h Transdermales Pflaster	not available	67845.00.00	HEXAL AG	DE
Fentanyl Sandoz 37,5 mikrogram/timme depotplåster	DE/H/1147/003	25589	SANDOZ A/S	SE
Fentanyl Sandoz 75 µg/h matrix transdermálna náplast	DE/H/0765/004	65/0050/07-S	SANDOZ PHARMACEUTICALS D.D.	SK
FENTANYL SANDOZ MATRIXPLEISTER 37 µG/UUR, PLEISTERS VOOR TRANSDERMAAL GEBRUIK	DE/H/1147/003	RVG 100320	SANDOZ B.V.	NL
FENTANYL/DEMO 0,05 mg/1 ml ενέσιμο διάλυμα	not available	19809/20-02-2020	DEMO ABEE	GR

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
FENTANYL/DEMO 0,5 mg/10 ml (0,05 mg/ml) ενέσιμο διάλυμα	not available	19808/20-02-2020	DEMO ABEE	GR
Fentanyl-HEXAL MAT 150 µg/h, transdermales Pflaster	DE/H/1047/002	68534.00.00	HEXAL AG	DE
Fentanyl-HEXAL MAT 37,5 µg/h, transdermales Pflaster	not available	67844.00.00	HEXAL AG	DE
Fentanyl-HEXAL MAT 37,5 µg/h, transdermales Pflaster	DE/H/1047/001	68584.00.00	HEXAL AG	DE
Fentanyl-HEXAL S 37,5 µg/h, transdermales Pflaster	DE/H/1146/003	69333.00.00	HEXAL AG	DE
Fentanyl-Piramal 0,05 mg/ml Injektionslösung	not available	BE 091996	PIRAMAL CRITICAL CARE B.V.	BE
Fentanyl-Piramal 0,05 mg/ml Injektionslösung	not available	BE 115412	PIRAMAL CRITICAL CARE B.V.	BE
Fentanyl-Piramal 0,05 mg/ml Injektionslösung	not available	1989011500	PIRAMAL CRITICAL CARE B.V.	LU
Fentanyl-Piramal 0,05 mg/ml Injektionslösung	not available	1989011501	PIRAMAL CRITICAL CARE B.V.	LU
Fentanyl-Piramal 0,05 mg/ml oplossing voor injectie	not available	BE 091996	PIRAMAL CRITICAL CARE B.V.	BE
Fentanyl-Piramal 0,05 mg/ml oplossing voor injectie	not available	BE 115412	PIRAMAL CRITICAL CARE B.V.	BE
Fentanyl-Piramal 0,05 mg/ml oplossing voor injectie	not available	BE 091996	PIRAMAL CRITICAL CARE B.V.	BE
Fentanyl-Piramal 0,05 mg/ml oplossing voor injectie	not available	BE 115412	PIRAMAL CRITICAL CARE B.V.	BE
Fentanyl-Piramal 0,05 mg/ml solution injectable	not available	BE 091996	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
Fentanyl-Piramal 0,05 mg/ml solution injectable	not available	BE 115412	PIRAMAL CRITICAL CARE B.V.	BE
Fentanyl-Piramal 0,1 mg – Ampullen	not available	17.049	PIRAMAL CRITICAL CARE B.V.	AT
Fentanyl-Piramal 0,1 mg, Injektionslösung	not available	6762282.01.00	PIRAMAL CRITICAL CARE B.V.	DE
Fentanyl-Piramal 0,5 mg – Ampullen	not available	16.948	PIRAMAL CRITICAL CARE B.V.	AT
Fentanyl-Piramal 0,5 mg, Injektionslösung	not available	6762282.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Fentanyl-Piramal oplossing voor injectie 0,05 mg/ml	not available	RVG 04748	PIRAMAL CRITICAL CARE B.V.	NL
Haldid, injektionsvæske, opløsning	not available	04239	PIRAMAL CRITICAL CARE B.V.	DK
Leptanal 50 mikróg/ml stungulyf, lausn.	not available	880082	PIRAMAL CRITICAL CARE B.V.	IS
LEPTANAL 50 mikrogram/ml injeksjonsvæske, oppløsning.	not available	7425	PIRAMAL CRITICAL CARE B.V.	NO
Leptanal 50 mikrogram/ml injektionsvätska, lösning	not available	10813	PIRAMAL CRITICAL CARE B.V.	SE
Mezolar Matrix 37.5 microgram/hour transdermal patch	DE/H/1147/003	PL 04416/0846	SANDOZ LTD	XI
Sublimaze	not available	PL 37071/0004	PIRAMAL CRITICAL CARE LIMITED	XI
Sublimaze 50 micrograms/ml, Solution for Injection	not available	PA22583/002/001	PIRAMAL CRITICAL CARE B.V.	IE
Tilotrans 100 microgram/hour transdermal patches	not available	PL 20416/0581	CRESCENT PHARMA LIMITED	XI
Tilotrans 25 microgram/hour	not available	PL 20416/0578	CRESCENT PHARMA LIMITED	XI

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transdermal patches				
Tilotrans 50 microgram/hour transdermal patches	not available	PL 20416/0579	CRESCENT PHARMA LIMITED	XI
Tilotrans 75 microgram/hour transdermal patches	not available	PL 20416/0580	CRESCENT PHARMA LIMITED	XI