31 October 2018
EMA/44220/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ondansetron

Procedure no.: PSUSA/00002217/201802

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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
Ondansetron B. Braun 0,08 mg/ml infusionsvätska, lösning	DE/H/0805/002	52598	B.BRAUN MELSUNGEN AG	SE
Ondansetron B. Braun 0,16 mg/ml infusionsvätska, lösning	DE/H/0805/003	52599	B.BRAUN MELSUNGEN AG	SE
Ondansetron B. Braun 0,08 mg/ml, oplossing voor infusie	DE/H/0805/002	RVG 116983	B.BRAUN MELSUNGEN AG	NL
Ondansetron B. Braun 0,16 mg/ml, oplossing voor infusie	DE/H/0805/003	RVG 116996	B.BRAUN MELSUNGEN AG	NL
Ondansetron B. Braun 0,16 mg/ml infuusioneste, liuos	DE/H/0805/003	33148	B.BRAUN MELSUNGEN AG	FI
Ondansetron B. Braun 0,16 mg/ml Infusionslösung	DE/H/0805/003	137414	B.BRAUN MELSUNGEN AG	AT
Ondansetron B. Braun 0,08 mg/ml solution pour perfusion	DE/H/0805/002	BE501120	B.BRAUN MELSUNGEN AG	BE
Ondansetron B. Braun 0,16 mg/ml, oplossing voor infusie	DE/H/0805/003	BE501137	B.BRAUN MELSUNGEN AG	BE
Ondansetron B. Braun 0,16 mg/ml solution pour perfusion	DE/H/0805/003	BE501137	B.BRAUN MELSUNGEN AG	BE
Ondansetron B. Braun 0,08 mg/ml, oplossing voor infusie	DE/H/0805/002	BE501120	B.BRAUN MELSUNGEN AG	BE
Ondansetron B. Braun 0,16 mg/ml Infusionslösung	DE/H/0805/003	94575.00.00	B.BRAUN MELSUNGEN AG	DE
Ondansetrón B. Braun 0,08 mg/ml solución para perfusión	DE/H/0805/002	81.830	B.BRAUN MELSUNGEN AG	ES

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
Ondansetrón B. Braun 0,16 mg/ml solución para perfusión	DE/H/0805/003	81.829	B.BRAUN MELSUNGEN AG	ES
Ondansetron B. Braun 0,08 mg/ml Infusionslösung	DE/H/0805/002	94574.00.00	B.BRAUN MELSUNGEN AG	DE
Ondansetron B. Braun 0,16 mg/ml infuzní roztok	DE/H/0805/003	20/444/16-C	B.BRAUN MELSUNGEN AG	CZ
Ondansetron B. Braun 0,08 mg/ml infuusioneste, liuos	DE/H/0805/002	33147	B.BRAUN MELSUNGEN AG	FI
Ondansetron Amneal 2 mg/ml injektionsvätska, lösning	DE/H/4540/001	53367	AMNEAL PHARMA EUROPE LIMITED	SE
Ondansetron Amneal 2 mg/ml Injektionslösung	DE/H/4540/001	95655.00.00	AMNEAL PHARMA EUROPE LIMITED	DE
Ondansetron B. Braun 8 mg Schmelztabletten	not available	66118.00.00	B.BRAUN MELSUNGEN AG	DE
Ondansetron B. Braun 4 mg Schmelztabletten	not available	66115.00.00	B. BRAUN MELSUNGEN AG	DE
Ondansetron B. Braun 8 mg Schmelztabletten	not available	2012050044	B. BRAUN MELSUNGEN AG ART 57	LU
Ondansetron B. Braun 0,16 mg/ml infúzny roztok	DE/H/0805/003	20/0485/16-S	B.BRAUN MELSUNGEN AG	SK
Ondansetron 4 mg film-coated tablets	not available	PL 36390/0013	CIPLA (EU) LIMITED	UK
Ondansetron 8 mg film-coated tablets	not available	PL 36390/0014	CIPLA (EU) LIMITED	UK
ONDANSETRON EG 8 mg, comprimé orodispersible	not available	NL32178	EG LABO LABORATOIRES EUROGENERICS	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
Ondansetron B. Braun 4 mg Schmelztabletten	not available	2012050043	B. BRAUN MELSUNGEN AG ART 57	LU
ONDANSETRON ZENTIVA 8 MG, COMPRIME ORODISPERSIBLE	not available	34009 300 878 4 8	SANOFI-AVENTIS FRANCE	FR
ONDANSETRON ZENTIVA 8 MG, COMPRIME ORODISPERSIBLE	not available	382 844-9	SANOFI-AVENTIS FRANCE	FR
ONDANSETRON ZENTIVA 8 MG, COMPRIME ORODISPERSIBLE	not available	34009 300 878 2 4	SANOFI-AVENTIS FRANCE	FR
ONDANSETRON ZENTIVA 8 MG, COMPRIME ORODISPERSIBLE	not available	382 840-3	SANOFI-AVENTIS FRANCE	FR
ONDANSETRON ZENTIVA 8 MG, COMPRIME ORODISPERSIBLE	not available	382 843-2	SANOFI-AVENTIS FRANCE	FR
ONDANSETRON ZENTIVA 8 MG, COMPRIME ORODISPERSIBLE	not available	34009 300 878 3 1	SANOFI-AVENTIS FRANCE	FR
ONDANSETRON ZENTIVA 8 MG, COMPRIME ORODISPERSIBLE	not available	34009 300 878 5 5	SANOFI-AVENTIS FRANCE	FR
ONDANSETRON ZENTIVA 8 MG, COMPRIME ORODISPERSIBLE	not available	382 842-6	SANOFI-AVENTIS FRANCE	FR
Ondansetron Amneal 2 mg/ml injektionsvätska, lösning	DE/H/4540/001	53367	AMNEAL PHARMA EUROPE LIMITED	SE
Ondansetron Amneal 2 mg/ml Injektionslösung	DE/H/4540/001	95655.00.00	AMNEAL PHARMA EUROPE LIMITED	DE
Ondansetron B.Braun 2 mg/ml solution injectable	DE/H/0805/001	BE316897	B.BRAUN MELSUNGEN AG	BE
Ondansetron B.Braun 2 mg/ml solution injectable	DE/H/0805/001	BE316881	B.BRAUN MELSUNGEN AG	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
Ondansetron B. Braun 2 mg/ml soluzione iniettabile o per infusione	DE/H/0805/001	038128029	B. BRAUN MELSUNGEN AG ART 57	IT
Ondansetron B. Braun 2 mg/ml soluzione iniettabile o per infusione	DE/H/0805/001	038128031	B. BRAUN MELSUNGEN AG ART 57	IT
Ondansetron B. Braun 2 mg/ml soluzione iniettabile o per infusione	DE/H/0805/001	038128043	B. BRAUN MELSUNGEN AG ART 57	IT
Ondansetron B. Braun 2 mg/ml soluzione iniettabile o per infusione	DE/H/0805/001	038128056	B. BRAUN MELSUNGEN AG ART 57	IT
Ondansetrom B. Braun 4 mg/2 ml solução injectável	DE/H/0805/001	5042825	B.BRAUN MELSUNGEN AG	PT
Ondansetrom B. Braun 8 mg/4 ml solução injectável	DE/H/0805/001	5042775	B.BRAUN MELSUNGEN AG	PT
Ondansetrom B. Braun 8 mg/4 ml solução injectável	DE/H/0805/001	5042809	B.BRAUN MELSUNGEN AG	PT
Ondansetrom B. Braun 8 mg/4 ml solução injectável	DE/H/0805/001	5442850	B.BRAUN MELSUNGEN AG	PT
Ondansetron B.Braun 2 mg/ml ενέσιμο διάλυμα	DE/H/0805/001	2806/15-1-2008	B.BRAUN MELSUNGEN AG	GR
Ondansetron B. Braun 2 mg/ml oplossing voor injectie	DE/H/0805/001	BE316881	B.BRAUN MELSUNGEN AG	BE
Ondansetron B. Braun 2 mg/ml oplossing voor injectie	DE/H/0805/001	BE316897	B.BRAUN MELSUNGEN AG	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**
Ondansetron B.Braun 2 mg/ml ενέσιμο διάλυμα	DE/H/0805/001	2807/15-1-2008	B.BRAUN MELSUNGEN AG	GR
Ondansetron B. Braun 2 mg/ml oplossing voor injectie	DE/H/0805/001	BE316881	B.BRAUN MELSUNGEN AG	BE
Ondansetron B.Braun 2 mg/ml solution injectable	DE/H/0805/001	BE316881	B.BRAUN MELSUNGEN AG	BE
Ondansetron B. Braun 2 mg/ml oplossing voor injectie	DE/H/0805/001	BE316897	B.BRAUN MELSUNGEN AG	BE
Ondansetron B.Braun 2 mg/ml solution injectable	DE/H/0805/001	BE316897	B.BRAUN MELSUNGEN AG	BE
Ondansetrom B. Braun 4 mg/2 ml solução injectável	DE/H/0805/001	5042817	B.BRAUN MELSUNGEN AG	PT
Ondansetron ”B. Braun”, injektionsvæske, opløsning	DE/H/0805/001	40588	B.BRAUN MELSUNGEN AG	DK
Ondansetron B. Braun 2 mg/ml injekční roztok	DE/H/0805/001	20/413/07-C	B.BRAUN MELSUNGEN AG	CZ
Ondansetron B. Braun 2 mg/ml injekčný roztok	DE/H/0805/001	20/0255/07-S	B.BRAUN MELSUNGEN AG	SK
Ondansetron B. Braun 2 mg/ml injektioneste, liuos	DE/H/0805/001	23137	B.BRAUN MELSUNGEN AG	FI
Ondansetron B. Braun 2 mg/ml injektionsvätska, lösning	DE/H/0805/001	24997	B.BRAUN MELSUNGEN AG	SE
Ondansetron B. Braun 2 mg/ml oplossing voor injectie	DE/H/0805/001	BE421644	B.BRAUN MELSUNGEN AG	BE
Ondansetron B. Braun 2 mg/ml roztwór do wstrzykiwań	DE/H/0805/001	15717	B.BRAUN MELSUNGEN AG	PL

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
Ondansetrón B. Braun 2 mg/ml solución inyectable EFG	DE/H/0805/001	69.905	B.BRAUN MELSUNGEN AG	ES
Ondansetron B. Braun 2 mg/ml, Injektionslösung	DE/H/0805/001	1-27392	B.BRAUN MELSUNGEN AG	AT
Ondansetron B. Braun 2 mg/ml, Injektionslösung	DE/H/0805/001	59057.00.00	B.BRAUN MELSUNGEN AG	DE
Ondansetron B. Braun 2 mg/ml, Injektionslösung	DE/H/0805/001	0667/08120021	B.BRAUN MELSUNGEN AG	LU
Ondansetron B. Braun 2 mg/ml, oplossing voor injectie	DE/H/0805/001	RVG 34936	B.BRAUN MELSUNGEN AG	NL
Ondansetron B. Braun 2 mg/ml soluzione iniettabile o per infusione	DE/H/0805/001	038128017	B. BRAUN MELSUNGEN AG ART 57	IT
Ondansetron B.Braun 2 mg/ml solution injectable	DE/H/0805/001	BE421644	B.BRAUN MELSUNGEN AG	BE
Ondansetron B.Braun 2 mg/ml ενέσιμο διάλυμα	DE/H/0805/001	2806/15-1-2008	B.BRAUN MELSUNGEN AG	GR
Ondansetrom B. Braun 4 mg/2 ml solução injectável	DE/H/0805/001	5042775	B.BRAUN MELSUNGEN AG	PT
Ondansetrom B. Braun 4 mg/2 ml solução injectável	DE/H/0805/001	5042809	B.BRAUN MELSUNGEN AG	PT
Ondansetrom B. Braun 4 mg/2 ml solução injectável	DE/H/0805/001	5442850	B.BRAUN MELSUNGEN AG	PT
Ondansetrom B. Braun 8 mg/4 ml solução injectável	DE/H/0805/001	5042817	B.BRAUN MELSUNGEN AG	PT
Ondansetrom B. Braun 8 mg/4 ml solução injectável	DE/H/0805/001	5042825	B.BRAUN MELSUNGEN AG	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**
Zofran Zydis 4 mg kylmäkuivattu tabletti	not available	12874	NOVARTIS FINLAND OY	FI
Zofran Zydis 4 mg frystorkad tablett	not available	12874	NOVARTIS FINLAND OY	FI
Zofran 2 mg/ml otopina za injekciju ili infuziju	not available	UP/I-530-09/12-02/325	NOVARTIS HRVATSKA D.O.O.	HR
Zofran 4 mg filmdragerad tablett	not available	10793	NOVARTIS FINLAND OY	FI
Zofran 4 mg filmom obložene tablete	not available	UP/I-530-09/12-02/327	NOVARTIS HRVATSKA D.O.O.	HR
Zofran 4 mg kalvopäällysteinen tabletti	not available	10793	NOVARTIS FINLAND OY	FI
Zofran 8 mg filmdragerad tablett	not available	10794	NOVARTIS FINLAND OY	FI
Zofran 8 mg filmom obložene tablete	not available	UP/I-530-09/12-02/328	NOVARTIS HRVATSKA D.O.O.	HR
Zofran 8 mg kalvopäällysteinen tabletti	not available	10794	NOVARTIS FINLAND OY	FI
Zofran 8 mg apvalkotās tabletes	not available	98-0741	NOVARTIS FINLAND OY	LV
Zofran 8 mg/4 ml šķīdums injekcijām	not available	98-0617	NOVARTIS FINLAND OY	LV
Zofran 2 mg/ml injektioneste, liuos	not available	10792	NOVARTIS FINLAND OY	FI
Zofran 2 mg/ml injektionsvätska, lösning	not available	10792	NOVARTIS FINLAND OY	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
Zofran Zydis 8 mg frystorkad tablett	not available	12875	NOVARTIS FINLAND OY	FI
Zofran Zydis 8 mg kylmäkuivattu tabletti	not available	12875	NOVARTIS FINLAND OY	FI
Zofran Zydis 8 mg Liofilizado oral	not available	3255486	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Zofran injekční roztok	not available	20/164/91-C	NOVARTIS, S.R.O.	CZ
Zofran čípky	not available	20/433/99-C	NOVARTIS, S.R.O.	CZ
ZOFRAN, 8 mg õhukese polümeerikattega tabletid	not available	215698	SIA "NOVARTIS BALTICS"	EE
Zofran 16 mg peräpuikko	not available	12319	NOVARTIS FINLAND OY	FI
Zofran 16 mg suppositorium	not available	12319	NOVARTIS FINLAND OY	FI
Zofran 16 mg suppositoires	not available	BE179417	NOVARTIS PHARMA N.V.	BE
Zofran 16 mg Zäpfchen	not available	BE179417	NOVARTIS PHARMA N.V.	BE
Zofran 16 mg zetpillen	not available	BE179417	NOVARTIS PHARMA N.V.	BE
Zofran Zydis, 4 mg, liofilizat doustny	not available	8879	NOVARTIS POLAND SP. Z O. O.	PL
Zofran Zydis, 8 mg, liofilizat doustny	not available	8880	NOVARTIS POLAND SP. Z O. O.	PL

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
Zofran 16 Zetpil, zetpillen 16 mg	not available	RVG 19252	NOVARTIS PHARMA B.V.	NL
Zofran 4 Zydis, smelttabletten 4 mg	not available	RVG 21471	NOVARTIS PHARMA B.V.	NL
Zofran 8 Zydis, smelttabletten 8 mg	not available	RVG 21472	NOVARTIS PHARMA B.V.	NL
Zofran, 16 mg, czopki	not available	8105	NOVARTIS POLAND SP. Z O. O.	PL
Zofran Stroop, stroop 4 mg/5 ml	not available	RVG 19922	NOVARTIS PHARMA B.V.	NL
Zofran, 4 mg/5 ml, syrop	not available	8106	NOVARTIS POLAND SP. Z O. O.	PL
ZOFRAN, 2 mg/ml süste- või infusioonilahus	not available	215498	SIA "NOVARTIS BALTICS"	EE
Zofran-Zydis 8 mg lyofilisaat voor oraal gebruik	not available	BE199193	NOVARTIS PHARMA N.V.	BE
Zofran-Zydis 8 mg lyophilisat oral	not available	BE199193	NOVARTIS PHARMA N.V.	BE
Zofran-Zydis 8 mg Lyophilisat zum Einnehmen	not available	BE199193	NOVARTIS PHARMA N.V.	BE
ЗОФРАН 2 mg/ml инжекционен разтвор	not available	20011016	NOVARTIS PHARMA GMBH	BG
Zofran 4 mg Potahované tablety	not available	20/165/91-A/C	NOVARTIS, S.R.O.	CZ
Zofran 8 mg Potahované tablety	not available	20/165/91-B/C	NOVARTIS, S.R.O.	CZ

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**
Zofran Zydis 8 mg Bukální tablety	not available	20/474/99-C	NOVARTIS, S.R.O.	CZ
ЗОФРАН 4 mg филмирани таблетки	not available	20011017	NOVARTIS PHARMA GMBH	BG
Zofran Zydis 4 mg Bukální tablety	not available	20/475/99-C	NOVARTIS, S.R.O.	CZ
ЗОФРАН 8 mg филмирани таблетки	not available	20011018	NOVARTIS PHARMA GMBH	BG
Zofran® 4 mg Filmtabletten	not available	22008.00.01	NOVARTIS PHARMA GMBH	DE
Zofran 16 mg Supositórios	not available	2504389	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Zofran 16 mg Supositórios	not available	2504488	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Zofran® Lösung	not available	37196.00.00	NOVARTIS PHARMA GMBH	DE
Zofran® 4 mg Zydis® Lingual	not available	41349.00.00	NOVARTIS PHARMA GMBH	DE
Zofran® 8 mg Zydis® Lingual	not available	41349.01.00	NOVARTIS PHARMA GMBH	DE
Zofran, 4 mg, tabletki powlekane	not available	R/0018	NOVARTIS POLAND SP. Z O. O.	PL
Zofran 4 Injectie, oplossing voor injectie 2 mg/ml (2 ml = 4 mg) / Zofran 8 Injectie, oplossing voor injectie 2 mg/ml (4 ml = 8 mg)	not available	RVG 14292	NOVARTIS PHARMA B.V.	NL

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**
Zofran 4 Injectie, oplossing voor injectie 2 mg/ml (2 ml = 4 mg) / Zofran 8 Injectie, oplossing voor injectie 2 mg/ml (4 ml = 8 mg)	not available	RVG 14293	NOVARTIS PHARMA B.V.	NL
Zofran, 8 mg, tabletki powlekane	not available	R/0019	NOVARTIS POLAND SP. Z O. O.	PL
Zofran® Syrup 4 mg/5 ml	not available	PL 00101/0980	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Zofran Injection 2 mg/ml	not available	16848	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Zofran Injection 2 mg/ml	not available	16849	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Zofran Konserveret	not available	13586	NOVARTIS HEALTHCARE A/S	DK
ZOFRAN® 4 mg-Filmtabletten	not available	1-19341	NOVARTIS PHARMA GMBH	AT
ZOFRAN® 8 mg-Filmtabletten	not available	1-19343	NOVARTIS PHARMA GMBH	AT
ZOFRAN-Lösung zum Einnehmen	not available	1-22404	NOVARTIS PHARMA GMBH	AT
Zofran	not available	17600	NOVARTIS HEALTHCARE A/S	DK
Zofran	not available	17601	NOVARTIS HEALTHCARE A/S	DK
Zofran Konserveret	not available	18966	NOVARTIS HEALTHCARE A/S	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
ZOFRAN Zydis 4 mg-Tabletten	not available	1-22512	NOVARTIS PHARMA GMBH	AT
ZOFRAN Zydis 8 mg-Tabletten	not available	1-22513	NOVARTIS PHARMA GMBH	AT
ZOFRAN-Zäpfchen	not available	1-22412	NOVARTIS PHARMA GMBH	AT
ZOPHREN 16 mg, suppositoire	not available	3400934387838	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 16 mg, suppositoire	not available	3400934388088	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 16 mg, suppositoire	not available	3400934388149	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 2 mg/ml, solution injectable en ampoule (IV).	not available	3400933539283	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 2 mg/ml, solution injectable en ampoule (IV).	not available	3400933539344	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400933538224	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400933538392	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400933538453	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400933538514	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400933538682	NOVARTIS PHARMA S.A.S.	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**
ZOPHREN 8 mg, comprimé pelliculé	not available	3400933538743	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400933538804	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400933538972	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400933539054	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400933539115	NOVARTIS PHARMA S.A.S.	FR
Zofran® 8 mg Filmtabletten	not available	22008.01.01	NOVARTIS PHARMA GMBH	DE
ZOFRON	not available	199060101	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060102	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060201	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060202	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060301	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060303	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060304	NOVARTIS (HELLAS) S.A.C.I.	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
ZOFRON	not available	199060305	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060306	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060401	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060403	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060404	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060405	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060406	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060501	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOPHREN 2 mg/ml, solution injectable en ampoule (IV).	not available	3400955683148	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 2 mg/ml, solution injectable en ampoule (IV).	not available	3400955683209	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 2 mg/ml, solution injectable en ampoule (IV).	not available	3400955683957	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 2 mg/ml, solution injectable en ampoule (IV).	not available	3400955684039	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 2 mg/ml, solution injectable en ampoule (IV).	not available	3400955684329	NOVARTIS PHARMA S.A.S.	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**
ZOPHREN 2 mg/ml, solution injectable en ampoule (IV).	not available	3400955684497	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400936163683	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400936163744	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400936163805	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400936163973	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400936164055	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400955685739	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400955685968	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400955686040	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400955686101	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400955686279	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400956473670	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, comprimé pelliculé	not available	3400956473731	NOVARTIS PHARMA S.A.S.	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
ZOPHREN 4 mg/5 ml, sirop	not available	3400934165634	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400936162044	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400936164116	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400936164284	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400936197282	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400936197343	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400955687511	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400955687689	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400955687740	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400955687801	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400955687979	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400956473960	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, comprimé pelliculé	not available	3400956474042	NOVARTIS PHARMA S.A.S.	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**
Zofran 16 mg végbélkúp	not available	OGYI-T-6559/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Zofran 16 mg végbélkúp	not available	OGYI-T-6559/02	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
ZOFRON	not available	199060601	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060801	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOFRON	not available	199060802	NOVARTIS (HELLAS) S.A.C.I.	GR
ZOPHREN 4 mg, lyophilisat oral	not available	3400934394461	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, lyophilisat oral	not available	3400934394522	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, lyophilisat oral	not available	3400934394690	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 4 mg, lyophilisat oral	not available	3400934394751	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, lyophilisat oral	not available	3400934394812	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, lyophilisat oral	not available	3400934394980	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, lyophilisat oral	not available	3400934395062	NOVARTIS PHARMA S.A.S.	FR
ZOPHREN 8 mg, lyophilisat oral	not available	3400934395123	NOVARTIS PHARMA S.A.S.	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
Zofran 16 mg suppositoires	not available	2007019170	NOVARTIS PHARMA N.V.	LU
Zofran 16 mg Suppositories	not available	PA0013/125/004	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Zofran 16 mg Zäpfchen	not available	2007019170	NOVARTIS PHARMA N.V.	LU
Zofran Zydis 4 mg burnoje disperguojamosios tabletės	not available	LT/1/03/3250/001	SIA "NOVARTIS BALTICS"	LT
Zofran Zydis 4 mg Oral Lyophilisate	not available	PA0013/125/007	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Zofran Zydis 8 mg burnoje disperguojamosios tabletės	not available	LT/1/03/3250/002	SIA "NOVARTIS BALTICS"	LT
Zofran Zydis 8 mg Oral Lyophilisate	not available	PA0013/125/008	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Zofran 0,8 mg/ml mixtúra, lausn	not available	IS/1/13/004/01	NOVARTIS HEALTHCARE A/S	IS
Zofran 16 mg, stikkpiller	not available	95-2484	NOVARTIS NORGE AS	NO
Zofran 2 mg/ml injektionsvätska, lösning	not available	11272	NOVARTIS SVERIGE AB	SE
Zofran 2 mg/ml stungulyf, lausn	not available	890110	NOVARTIS HEALTHCARE A/S	IS
Zofran 4 mg comprimidos recubiertos con película	not available	59.069	NOVARTIS FARMACÉUTICA S.A.	ES
Zofran 4 mg filmdragerade tabletter	not available	11493	NOVARTIS SVERIGE AB	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
Zofran 4 mg filmsko obložene tablete	not available	H/92/01707/003	NOVARTIS PHARMA GMBH	SI
Zofran 4 mg filmuhúðaðar töflur	not available	890111	NOVARTIS HEALTHCARE A/S	IS
Zofran 4 mg plėvele dengtos tabletės	not available	LT/1/94/1091/001	SIA "NOVARTIS BALTICS"	LT
Zofran 4 mg plėvele dengtos tabletės	not available	LT/1/94/1091/002	SIA "NOVARTIS BALTICS"	LT
Zofran 4 mg plėvele dengtos tabletės	not available	LT/1/94/1091/003	SIA "NOVARTIS BALTICS"	LT
Zofran 4 mg solución inyectable	not available	59.071	NOVARTIS FARMACÉUTICA S.A.	ES
Zofran 4 mg solución inyectable	not available	59.072	NOVARTIS FARMACÉUTICA S.A.	ES
Zofran 4 mg, tabletter	not available	7758	NOVARTIS NORGE AS	NO
Zofran 4mg Film-coated Tablets	not available	PA0013/125/005	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Zofran 4mg/5ml Syrup	not available	PA0013/125/003	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Zofran 8 mg comprimidos recubiertos con película	not available	59.070	NOVARTIS FARMACÉUTICA S.A.	ES
Zofran 8 mg filmdragerade tabletter	not available	11494	NOVARTIS SVERIGE AB	SE
Zofran 8 mg filmuhúðaðar töflur	not available	890112	NOVARTIS HEALTHCARE A/S	IS

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**
Zofran 8 mg plėvele dengtos tabletės	not available	LT/1/94/1091/004	SIA "NOVARTIS BALTICS"	LT
Zofran 8 mg plėvele dengtos tabletės	not available	LT/1/94/1091/005	SIA "NOVARTIS BALTICS"	LT
Zofran 8 mg, tabletter	not available	7700	NOVARTIS NORGE AS	NO
Zofran 8mg Film-coated Tablets	not available	PA0013/125/006	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Zofran injeksjonsvæske 2 mg/ml, oppløsning	not available	7699	NOVARTIS NORGE AS	NO
Zofran Tablets 8mg	not available	088/05201	NOVARTIS IRELAND LIMITED	MT
Zofran Zydis 4 mg liofilizado oral	not available	62.944	NOVARTIS FARMACÉUTICA S.A.	ES
Zofran-Zydis 8 mg lyophilisat oral	not available	2007019172	NOVARTIS PHARMA N.V.	LU
Zofran-Zydis 8 mg Lyophilisat zum Einnehmen	not available	2007019172	NOVARTIS PHARMA N.V.	LU
Zofran Suppositories 16 mg	not available	PL 00101/0979	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Zofran® Tablets 4 mg	not available	PL 00101/0981	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Zofran® Tablets 8 mg	not available	PL 00101/0982	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Zofran Melt 4 mg	not available	PL 00101/0983	NOVARTIS PHARMACEUTICALS UK LIMITED	UK

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**
Zofran® Injection 2 mg/ml	not available	PL 00101/0985	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Zofran 0,8 mg/ml oral lösning	not available	13433	NOVARTIS SVERIGE AB	SE
Zofran munlöslig 4 mg frystorkad tablett	not available	13585	NOVARTIS SVERIGE AB	SE
Zofran munlöslig 8 mg frystorkad tablett	not available	13586	NOVARTIS SVERIGE AB	SE
Zofran 2 mg/ml injektionsvätska, lösning	not available	14651	NOVARTIS SVERIGE AB	SE
Avessaron 4 mg Injektionslösung	not available	2007019174	NOVARTIS PHARMA N.V.	LU
Avessaron 4 mg Injektionslösung	not available	2007019175	NOVARTIS PHARMA N.V.	LU
Avessaron 4 mg solution injectable	not available	2007019174	NOVARTIS PHARMA N.V.	LU
Avessaron 4 mg solution injectable	not available	2007019175	NOVARTIS PHARMA N.V.	LU
ZOFRAN 4 mg-Ampullen	not available	1-19340	NOVARTIS PHARMA GMBH	AT
ZOFRAN 8 mg-Ampullen	not available	1-19342	NOVARTIS PHARMA GMBH	AT
Avessaron 4 mg Injektionslösung	not available	BE150236	NOVARTIS PHARMA N.V.	BE
Avessaron 4 mg Injektionslösung	not available	BE150263	NOVARTIS PHARMA N.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**
Avessaron 4 mg oplossing voor injectie	not available	BE150236	NOVARTIS PHARMA N.V.	BE
Avessaron 4 mg oplossing voor injectie	not available	BE150263	NOVARTIS PHARMA N.V.	BE
Avessaron 4 mg solution injectable	not available	BE150236	NOVARTIS PHARMA N.V.	BE
Avessaron 4 mg solution injectable	not available	BE150263	NOVARTIS PHARMA N.V.	BE
Zofran 4 mg Injektionslösung	not available	BE150272	NOVARTIS PHARMA N.V.	BE
Zofran 4 mg Injektionslösung	not available	BE150297	NOVARTIS PHARMA N.V.	BE
Zofran 4 mg oplossing voor injectie	not available	BE150272	NOVARTIS PHARMA N.V.	BE
Zofran 4 mg oplossing voor injectie	not available	BE150297	NOVARTIS PHARMA N.V.	BE
Zofran 4 mg solution injectable	not available	BE150272	NOVARTIS PHARMA N.V.	BE
Zofran 4 mg solution injectable	not available	BE150297	NOVARTIS PHARMA N.V.	BE
Zofran 4 mg Injektionslösung	not available	2007019167	NOVARTIS PHARMA N.V.	LU
Zofran 4 mg Injektionslösung	not available	2007019168	NOVARTIS PHARMA N.V.	LU
Zofran 4 mg solution injectable	not available	2007019167	NOVARTIS PHARMA N.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
Zofran 4 mg solution injectable	not available	2007019168	NOVARTIS PHARMA N.V.	LU
Zofran	not available	18515	NOVARTIS HEALTHCARE A/S	DK
Zofran	not available	18516	NOVARTIS HEALTHCARE A/S	DK
Zofran Zydis 8 mg liofilizado oral	not available	62.945	NOVARTIS FARMACÉUTICA S.A.	ES
Zofran 0,8 mg/ml, mikstur	not available	95-2485	NOVARTIS NORGE AS	NO
Zofran Flexi-amp Injection 2 mg/ml	not available	PL 00101/0985	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Zofran 4mg/2ml Solution for Injection or Infusion	not available	PA0013/125/001	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Zofran 8mg/4ml Solution for Injection or Infusion	not available	PA0013/125/002	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Zofran® i.v. 4 mg 4 mg/2 ml Injektionslösung	not available	22008.00.00	NOVARTIS PHARMA GMBH	DE
Zofran® i.v. 8 mg 8 mg/4 ml Injektionslösung	not available	22008.01.00	NOVARTIS PHARMA GMBH	DE
Zofran 4 mg/2 ml injekcinis ar infuzinis tirpalas	not available	LT/1/94/1091/006	SIA "NOVARTIS BALTICS"	LT
Zofran 4 mg/2 ml injekcinis ar infuzinis tirpalas	not available	LT/1/94/1091/007	SIA "NOVARTIS BALTICS"	LT
Zofran 8 mg/4 ml injekcinis ar infuzinis tirpalas	not available	LT/1/94/1091/008	SIA "NOVARTIS BALTICS"	LT

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
Zofran 8 mg/4 ml injekcinis ar infuzinis tirpalas	not available	LT/1/94/1091/009	SIA "NOVARTIS BALTICS"	LT
Zofran 4 mg, smeltetabletter	not available	96-3183	NOVARTIS NORGE AS	NO
Zofran 8 mg, smeltetabletter	not available	96-3184	NOVARTIS NORGE AS	NO
Zofran, 2 mg/ml, roztwór do wstrzykiwań	not available	R/0020	NOVARTIS POLAND SP. Z O. O.	PL
Zofran 0,8 mg/ml Xarope	not available	2504280	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Zofran 4mg/2ml Solution for Injection or Infusion	not available	088/05202	NOVARTIS IRELAND LIMITED	MT
Zofran 4mg/2ml Solution for Injection or Infusion	not available	088/05203	NOVARTIS IRELAND LIMITED	MT
Zofran Melt 8 mg	not available	PL 00101/0984	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
ZOFRAN 4 mg Compresse rivestite con film	not available	027612011	NOVARTIS FARMA S.P.A.	IT
ZOFRAN 8 mg Compresse rivestite con film	not available	027612023	NOVARTIS FARMA S.P.A.	IT
ZOFRAN 4 mg Compresse orodispersibili	not available	027612098	NOVARTIS FARMA S.P.A.	IT
ZOFRAN 8 mg Compresse orodispersibili	not available	027612112	NOVARTIS FARMA S.P.A.	IT
ZOFRAN 4 mg/5 ml Sciroppo	not available	027612086	NOVARTIS FARMA S.P.A.	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**
ZOFRAN 4 mg/2 ml Soluzione iniettabile	not available	027612035	NOVARTIS FARMA S.P.A.	IT
ZOFRAN 8 mg/4 ml Soluzione iniettabile	not available	027612047	NOVARTIS FARMA S.P.A.	IT
ZOFRAN 40 mg/20 ml Soluzione iniettabile	not available	027612136	NOVARTIS FARMA S.P.A.	IT
ZOFRAN 16 mg Supposte	not available	027612074	NOVARTIS FARMA S.P.A.	IT