

ANNESS I

**LISTA TAL-ISMIJET, QAWWIET TAL-PRODOTTI MEDICINALI
VETERINARJI, SPEĊI TA' ANNIMALI, MNEJN JINGHATA, DOŻA
RAKKOMANDATA U DETENTURI TAL-AWTORIZZAZZJONI GHAT-TQEGHID
FIS-SUQ FL-ISTATI MEMBRI**

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Awstrija	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec injection Injektionslön g für Rinder und Schweine	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Awstrija	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Awstrija	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
L-Awstrija	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Awstrija	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 10 mg/ml Injektionssus pension für Rinder, Schafe und Schweine	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Awstrija	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin – Injektionslös- ung für Tiere	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Awstrija	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
L-Awstrija	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Injektionslös- ung Für Tiere: Rinder, Schafe, Schweine	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Awstrija	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Injektionlösu- ng für Rinder	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Il-Belġju	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	BOVIMEC B	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Belġju	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN 10MG/ML	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Belġju	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN CATTLE	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Belġju	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	IVOMECE F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Il-Belġju	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Belġju	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC 1 % Solution injectable	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Il-Belġju	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC F solution injectable	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
Il-Belġju	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	Ivomec	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Il-Belġju	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	QUALIMEC 10MG/ML	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Belġju	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Oplossing voor Injectie voor rundvee	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Il-Bulgarija	Intervet International B.V. Wim de Korvrstraat 35, 5831 AA, Boxmeer, The Netherlands	Ivotan LA	Ivermectin 10 mg/ml	Frat, Nagħaġ, Moghoż, Hnieżer	Subkutanju	Frat, Nagħaġ, Moghoż: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Bulgarija	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1% injectable solution	Ivermectin 10 mg/ml	Frat, Nagħaġ, Moghoż, Hnieżer	Subkutanju	Frat, Nagħaġ, Moghoż: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Bulgarija	Alfasan International B.V., P.O. Box 78, 3440 AB Woerden, The Netherlands	Alfamec 1 %	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Bulgarija	BIOVET JSC 39 Petar Rakov Str. 4550 Pesthera Bulgaria	Pandex 1 %	Ivermectin 10 mg/ml	Frat, Naghaġ, Moghoż, Hnieżer	Subkutanju	Frat, Naghaġ, Moghoż: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Bulgarija	Centrovvet Ltd. Av.Los Cerrilos 602 Santiago, Chile	Microdes Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Il-Bulgarija	Interchemie werken “de Adelaar” BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Frat, Naghaġ, Moghoż, Hnieżer	Subkutanju	Frat, Naghaġ, Moghoż: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Bulgarija	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	Promectine	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Bulgarija	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ċipru	Panchris Feeds Ltd. P.O.Box 40261, 6302 Larnaca Cyprus	Bimectin Injection	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ċipru	Vetagric Ltd 3 Othellou Street, 2540 Dhali Industrial Estate Nicosia Cyprus	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Ċipru	Spyros Stavrinides Chemicals Ltd 28 Stasinou Avenue, 1060 Nicosia, Cyprus	Noromectin injection	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Ċeka	Vétoquinol s.r.o., Zámečnická 411, 288 02 Nymburk, Czech Republic	Biomectin 1 %	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Ċeka	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Ċeka	CEVA Animal Health Slovakia, spol. s r.o. Račianska 77 83 102 BRATISLAVA Slovak Republic	Cevamec 1 % inj. ad us. vet.	Ivermectin 10 mg/ml	Frat, Nagħaġ, Mogħoż, Hnieżer	Subkutanju	Frat, Nagħaġ, Mogħoż: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Ċeka	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1 %	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
Ir-Repubblika Ċeka	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1% inj. ad. us. vet.	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Ċeka	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Super inj. a.u.v.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Ir-Repubblika Ċeka	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Inj ad us vet	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Ċeka	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec inj. ad us. vet.	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Ċeka	Bioveta a.s., Komenského 212 683 23 Ivanovice na Hané Czech Republic	Biomec 10 mg/ml Injekční roztok	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
Ir-Repubblika Ċeka	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin injekċni roztok pro skot	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Id-Danimarka	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Id-Danimarka	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec Vet	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Id-Danimarka	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimec Vet	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Id-Danimarka	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomec vet.	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
Id-Danimarka	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Ivermectin "Virbac" Vet., injektionsvæs ke, opløsning	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Id-Danimarka	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Coopermec Vet	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Id-Danimarka	Merial Norden A/S Mileparken 20 E 2740 Skovlunde Id-Danimarka	Ivomec vet., injektionsvæs ke 10 mg/ml	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Estonja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Estonja	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1% injection, süstelahus	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Estonja	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Bimectin injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Estonja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Estonja	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1% injectable solution	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Estonja	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Estonja	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Finlandja	Scanvet Eläinlääkkeet Oy PL 27 13721 PAROLA Finland	Animec vet	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Finlandja	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimectin vet	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Finlandja	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 10 mg/ml vet injektioneste, liuos	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Finlandja	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec injection 10 mg/ml solution for injection	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Finlandja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet 10mg/ml Solution for Injection	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Finlandja	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC VET 10 mg/ml injektioneste, liuos	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Franza	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Franza	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEK D	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Franza	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1° Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC SOLUTION INJECTABLE POUR BOVINS	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Franza	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1° Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC D SOLUTION INJECTABLE	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Franza	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1° Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Solution Injectable pour Bovins Porçins Ovins	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Franza	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	IVERMECTIN ECO 10 MG/ML SOLUTION INJECTABLE	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Franza	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	QUALIMEC 10 MG/ML SOLUTION INJECTABLE	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Franza	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN BOVIN	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Franza	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	CEVAMEC BOVINS OVINS SOLUTION INJECTABLE	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Franza	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Magamectine iInjectable, solution injectable	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Franza	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Medimec Injectable, Solution Injectable	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Franza	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% Solution Injectable Bovine, Porcins	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Franza	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectine Solution Injectable pour bovins	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Franza	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Ġermanja	MERIAL GmbH Am Söldnermoos 6 D-85399 Hallbergmoos Germany	Ivomec	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Ġermanja	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injektion	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Ġermanja	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Diapec R	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Ġermanja	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Wedemec R	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Ġermanja	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumex Injektion für Rinder	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Ġermanja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1% Injektion	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Ġermanja	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Inektionslösu ng	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Greċja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% 1% Ενέσιμο Διάλυμα	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Greċja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1% 1% Ενέσιμο Διάλυμα	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Greċja	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Greċja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTI N	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Greċja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Greċja	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Inj. Sol.	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Greċja	VETERIN ABEE Aspropyrgos Attikis 19300 Greece	VETERMEC	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Greċja	PNG Gerolymatos S.A. 13, Asklipiou 145 68 KRYONERI, ATTICA Greece	VALANEQ	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Greċja	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	MAXIMEC	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Greċja	SCHERING PLOUGH SA 65,Ag Dimitriou 17455, Athens Greece	TIZOVAL	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Ungerija	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	Bayer Hungária Ltd. H-1123 Budapest Alkotás u. 50. Hungary	Baymec Trio 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
L-Ungerija	Ceva-Phylaxia Oltóanyagtermelő Zrt. Szállás u. 5 1107 Budapest Hungary	Cevamec 1% injekció A.U.V	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	Divasa Farmavic Hungaria Ltd. H-6070 Izsák, Kossuth L. u. 60. Hungary	ECOMECTI N	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	Bremer Pharma GmbH. Werkstrasse 42 34414 Warburg-Scherfede Germany	FROMMEC TIN	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	IVERGEN PREMIUM LA	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	Veterina Polska Sp. Zo.o. Ul. Mogilska 80, 31546 Krakow Poland	Iverktin Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	VMD Animal Health Ltd. Közraktár u. 22/b. II. 3., 1093 Budapest Hungary	IVERVETo 1 %	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
L-Ungerija	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec injekció A.U.V.	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec super injekció A.U.V.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
L-Ungerija	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Ungerija	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Vetimec 10 mg/ml solution for injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Kilo-mec 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Mastermectin 1 Per Cent	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
L-Irlanda	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Coopermec 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Injectable Solution	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec for Cattle Swine and Sheep 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Super Solution for Injection	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
L-Irlanda	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Panomec 1% Solution for Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
L-Irlanda	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Classic Injection for Cattle and Sheep 1% w/v	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
L-Irlanda	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Fatromectin 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
L-Irlanda	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanimec Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec 1% solution Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumex Injection for Cattle, 1%, Solution for injection for cattle	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Anisec Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Aniject Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chaniject Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumiject Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Medimec Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Topimec Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin 1.0 %w/v Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Irlanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Mectaject 1.0 % Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bovimectin 1% solution for injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injection for Cattle & Sheep	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Trimectin Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bovimec 1.0% w/v Solution for Injection for Cattle	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Irlanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Primectin 1% w/v Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Solution for Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
L-Irlanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Enovex Injection 1% w/v	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Irlanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Irlanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closiver Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
L-Iżlanda	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec vet.	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Italja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Baymec 1% Soluzione	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Italja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Italja	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin cattle	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Italja	INTERVET PRODUCTIONS SRL Via Nettunense km 20, 300 04011 Aprilia Italy	Ivogell	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Italja	Merial Italia S.p.A. a Socio Unico, Via Vittor Pisani, 16 Milano Italy	Ivomec	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Italja	Merial Italia S.p.A. a Socio Unico, Via Vittor Pisani, 16 Milano Italy	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
L-Italja	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec iniettable	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Italja	Fatro Via Emilia, 285 40064 Ozzano Emilia (Bologna) Italy	Tolomec	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Italja	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Soluzione iniettabile	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Italja	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC F soluzione iniettabile	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
L-Italja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Soluzione iniettabile per bovini	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
L-Italja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1% Solution for Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Latvja	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Latvja	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Bimectin Injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Latvja	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Latvja	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1%	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Latvja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 10 mg/ml	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer 300 µg ivermectin/kg bw
Il-Latvja	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEK 1% Injection	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Latvja	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Il-Latvja	Pharmaceutical Company PFO "VETOS-FARMA" sp. z.o.o., Dzierzoniwska street 21 58-260 Bielawa Poland	Iwermektyna 1% Injection	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Latvja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Litwanja	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEC PLUS, injekcinis tirpalas	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Il-Litwanja	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEC 1%, injekcinis tirpalas	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Litwanja	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%, injekcinis tirpalas	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Litwanja	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1%, injekcinis tirpalas	Ivermectin 10 mg/ml	Frat, Nagħaġ, Moghoż, Hnieżer	Subkutanju	Frat, Nagħaġ, Moghoż: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Litwanja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injekcinis tirpalas	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Litwanja	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	PROMECTINE	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Litwanja	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	BIMECTIN	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Litwanja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN 10 mg/ml	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Lussemburgu	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	Ivomec solution pour injection	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Il-Lussemburgu	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1%	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Lussemburgu	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% inj.sol. bovine and porcine	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer 300 µg ivermectin/kg bw
Il-Lussemburgu	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1% solution for injection	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Lussemburgu	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 1% solution for injection	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Il-Lussemburgu	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec solution pour injection bovine	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Malta	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Malta	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	Iveripra-I	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Malta	Interchemie werken “de Adelaar” BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Frat, Nagħaġ, Moghoż, Hnieżer	Subkutanju	Frat, Nagħaġ, Moghoż: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Malta	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Malta	INDUSTRIAL VETERINARIA, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat Barcelona Spain	Promectine	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Olanda	Merial B.V. Kleermakerstraat 10 1991 JL Velsersbroek The Netherlands	Ivomec	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Olanda	Merial B.V. Kleermakerstraat 10 1991 JL Velsersbroek The Netherlands	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Olanda	Merial B.V. Kleermakerstraat 10 1991 JL Velserbroek The Netherlands	Panomec Injectievloeis tof	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Olanda	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec Injection	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Olanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Euromec Injectie	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Olanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injectie	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Olanda	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injectie	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
L-Olanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injectie	Ivermectin 10 mg/ml	Frat, Ħnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Ħnieżer: 300 µg ivermectin/kg bw
L-Olanda	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin Cattle	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
L-Olanda	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin Injectie	Ivermectin 10 mg/ml	Frat, Ħnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Ħnieżer: 300 µg ivermectin/kg bw
L-Olanda	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
L-Olanda	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ges-o-mec 10mg/ml oplossing voor injectie	Ivermectin 10 mg/ml	Frat, Nagħaġ, Ħnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Ħnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Olanda	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10mg/g solution for injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Olanda	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands	Iverveto 1%	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
In-Norveġja	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec vet, injeksjonsvæ ske, oppløsning 10 mg/ml	Ivermectin 10 mg/ml	Frat, Naghaġ, Ċriev, Hnieżer	Subkutanju	Frat, Naghaġ, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
In-Norveġja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet Injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
In-Norveġja	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC VET	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Polonja	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Polonja	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1%	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Polonja	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. ul. Grójecka 6 05-651 Drwalew Poland	Ivermina 1% Inj	Ivermectin 10 mg/ml	Frat, hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Polonja	Pharmaceutical Company PFO "VETOS-FARMA" sp. z.o.o., Dzierzoniwska street 21 58-260 Bielawa Poland	Iwermektyna 1% Iniekcja	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Polonja	Agri- Biovet Sp. z o.o. ul. Smocza 27 01-048 Warsaw Poland	Pandex 1%	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Polonja	Scan Vet Poland Sp. z o.o. Skierszewo, ul. Kiszowska 9 62-200 Gniezno Poland	Paramectin 1%	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Polonja	Przedsiębiorstwo Wielobranżowe Vet Agro Sp. z o.o. ul. Gliniana 32 20-616 Lublin Poland	Vetamectin	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Portugall	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Tizoval Bovinos 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Portugall	Calier Portugal S.A Centro Empresarial Sintra-Estoril II, Ed. C, R. Pé de Mouro Estrada de Albarraque 2710 - 335 Sintra Portugal	Ivertin	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Portugall	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injectável	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Portugall	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injectável para bovinos e ovinos 1%	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Portugall	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1% Sol Injectável	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Portugall	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Vectimax 10 mg/ML Sol. Inj. Este é	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Portugall	Merial Portuguesa - Saúde Animal, Lda AV Maria Lamas, Lote 19 - BL - A Piso 2 Parque Industrial Comercial Serra das Minas 2635-432 Rio de Mouro Portugal	Ivomec F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Il-Portugall	Merial Portuguesa - Saúde Animal, Lda AV Maria Lamas, Lote 19 - BL - A Piso 2 Parque Industrial Comercial Serra das Minas 2635-432 Rio de Mouro Portugal	Ivomec 1% Bovinos, Solução Injectável	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Il-Portugall	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injectável 1%	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Il-Portugall	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injectável 1%	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Portugall	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec F, Solução Injectável 1mg/ml	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Il-Portugall	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC, Solução injectavel	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Il-Portugall	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin FF, solução injectável para bovinos	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Ir-Rumanija	ANTIBIOTICE IASI S.A. Str. Valea Lupului, nr. 1, Iași, jud. Iași Romania	Ivermectina 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Rumanija	BIOWET GORZOW PHARMACEUTICALS COMPANY- Kosynierów Gdyńskich 13/14 ST., Gorzow WLPK Poland	Biomectin 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	BIOVET JSC 39 Petar Rakov Str. 4550 Pesthera Bulgaria	Pandex 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	Bioveta a.s., Komenského 212 683 23 Ivanovice na Hané Czech Republic	Biomec inj.	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	CEVA SANTE ANIMALE Str. Chindiei, nr. 5 Sector 4 040185 Bucureşti Romania	Cevamec 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	DAR AL DAWA VETERINARY & AGRICULTURAL INDUSTRIAL Co. LTD. Jordan NA UR 11710 PO BOX 285 Jordania	Ivodad 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Rumanija	DUTCH FARM VETERINARY PHARMACEUTICALS B.V. Veemweg 1-3771 MT BARNEVELEND The Netherlands	Dufamec 1% inj.	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1% injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	FARMAVET S.A. Str. Petricani 198, Chişinău Republica Moldova	Ivermectina 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	HEMOFARM – HEMOVET Beogradski Put BB Vrsac Serbia	Ivermektin S	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	Iveripra I	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	Interchemie werken “de Adelaar” BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Rumanija	INTERVET PRODUCTIONS SRL Via Nettunense km 20, 300 04011 Aprilia Italy	Ivogell	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	INTERVET ROMANIA S.R.L. Șoseaua de Centură, nr. 27-28, 077040 Chiajna, Ilfov Romania	Ivotan LA	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	PANTEX Ganzestaartsedijk 8 – 5525 KC Duizel The Netherlands	Panmectin 10	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	PASTEUR – Filiala Filipești Str. Principală, nr. 944, Filipeștii de Pădure, Jud. Prahova Romania	Evomec	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7, Voluntari Romania	Romivermect in B ₁ 1%	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Rumanija	SYVA Av. Párroco Pablo Diez, 49 – 57 24010 – Leon Spain	Zoomectin	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Rumanija	VMD Animal Health Ltd. Közraktár u. 22/b. II. 3., 1093 Budapest Hungary	Iverveto 1% Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Repubblika Slovakka	Vétoquinol s.r.o., Zámečnická 411, 288 02 Nymburk, Czech Republic	Biomectin	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Slovakka	CEVA Animal Health Slovakia, spol. s r.o. Račianska 77 83 102 BRATISLAVA Slovak Republic	Cevamec 1 % inj. ad us. vet.	Ivermectin 10 mg/ml	Frat, Nagħaġ, Mogħoż, Hnieżer	Subkutanju	Frat, Nagħaġ, Mogħoż: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Slovakka	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection ad us vet	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Slovakka	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1% inj. ad us.vet.	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Repubblika Slovakka	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Super inj. ad us.vet.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Repubblika Slovakkja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Frat, Naghaġ, Hniežer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hniežer: 300 µg ivermectin/kg bw
Ir-Repubblika Slovakkja	Pharmagal spol.s.r.o. Murgašova 5 949 01 Nitra Slovak Republic	Galmectin	Ivermectin 10 mg/ml	Frat, Naghaġ, Hniežer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hniežer: 300 µg ivermectin/kg bw
Ir-Repubblika Slovakkja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin injekčný roztok pre hovädzi dobytok	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Is-Slovenja	VET4VET d.o.o. Gerbičeva 50, 1000 Ljubljana Slovenia	Animec Injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hniežer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hniežer: 300 µg ivermectin/kg bw
Is-Slovenja	VETERINA Plus d.o.o., Dunajska 51, 1000 Ljubljana, Slovenia	IVERKTIN 1% solution for injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hniežer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hniežer: 300 µg ivermectin/kg bw
Is-Slovenja	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEC solution for injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hniežer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hniežer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
Spanja	DIVASA FARMAVIC, S.A. Ctra. Sant Hipolit, km 71 08503 – Gurb-Vic Barcelona Spain	DIVAMECT IN 1% SOLUCION	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Spanja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% Solution Injectable para Bovino y Porcino	Ivermectin 10 mg/ml	Frat, Ħnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Ħnieżer: 300 µg ivermectin/kg bw
Spanja	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC SOLUCIÓN INYECTAB LE PARA BOVINOS	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Spanja	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	TIZOVAL VACUNO INYECTAB LE	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Spanja	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	CHANECTI N INYECTAB LE	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Spanja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injectable	Ivermectin 10 mg/ml	Frat, Ħnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Ħnieżer: 300 µg ivermectin/kg bw
Spanja	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN BOVINO	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Spanja	INDUSTRIAL VETERINARIA, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat Barcelona Spain	PROMECTI NE	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Spanja	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	SUMEX INYECTAB LE BOVINO	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Spanja	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	IVERIPRA-I	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Spanja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTI N 10 MG/ML SOLUCION INYECTABLE	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Spanja	Chemo Iberica Gran Via Carlos III, 98 – 7 th floor. 08028 Barcelona, Spain	BOVECTIN	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Spanja	MERIAL LABORATORIOS S.A Tarragona, 161-Locales D/E 08014 Barcelona Spain	Ivomec Injectable Para Vacuno	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Spanja	MERIAL LABORATORIOS S.A Tarragona, 161-Locales D/E 08014 Barcelona Spain	Ivomec F Injectable Para Vacuno	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Spanja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Solucion injectable para bovino	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
L-Iżvezja	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec® vet.	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
L-Iżvezja	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2 2080-104 Almeirim Portugal	Virbamec vet. 10 mg/ml injektionsväts ka, lösning	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Iżvezja	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimectin® vet.	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Iżvezja	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin vet Solution for Injection 10mg/ml	Ivermectin 10 mg/ml	Frat, Ċriev, Hnieżer	Subkutanju	Frat, Ċriev: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Iżvezja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin, 10 mg/ml, Injektionsvät ska, lösning	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
L-Iżvezja	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec, 10 mg/ml, Injektionsvät ska, lösning	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Renju Unit	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin Cattle	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Renju Unit	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Classic Injection for Cattle and Sheep	Ivermectin 10 mg/ml	Frat, Nagħaġ	Subkutanju	200 µg ivermectin/kg bw
Ir-Renju Unit	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Ir-Renju Unit	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Panomec Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Frat, Nagħaġ, Ħnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Ħnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec Injection	Ivermectin 10 mg/ml	Frat, Ħnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Ħnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Renju Unit	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1° Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Injectable Solution For Cattle and Swine	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1° Andar, Sala, 22080-104 Almeirim Portugal	Virbamec Injectable Solution for Cattle, Swine and Sheep	Ivermectin 10 mg/ml	Frat, Naghag, Hnieżer	Subkutanju	Frat, Naghag: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1° Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Super	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Ir-Renju Unit	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Enovex Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Renju Unit	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Frat, Naghag, Hnieżer	Subkutanju	Frat, Naghag: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' annimal	Mnejn jinghata	Doża rakkomandata
Ir-Renju Unit	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injection	Ivermectin 10 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw
Ir-Renju Unit	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin 1% w/v Solution for Injection	Ivermectin 10 mg/ml	Frat, Nagħaġ, Hnieżer	Subkutanju	Frat, Nagħaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Ecomec 1% Injection	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Qualimintic 1% Injection	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Renju Unit	Alstoe Ltd Sheriff Hutton Industrial Park Sheriff Hutton York YO60 6RZ United Kingdom	Alstomec	Ivermectin 10 mg/ml	Frat, Hnieżer	Subkutanju	Frat: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Frat, Naghaġ, Hnieżer	Subkutanju	Frat, Naghaġ: 200 µg ivermectin/kg bw Hnieżer: 300 µg ivermectin/kg bw
Ir-Renju Unit	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Ir-Renju Unit	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closiver Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw

Stat Membru	Detentur tal-Awtorizzazzjoni ghat-Tqeghid fis-Suq u Indirizz	Isem ivvintat	Qawwiet	Speċi ta' animal	Mnejn jinghata	Doża rakkomandata
Ir-Renju Unit	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Norofas Solution for Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Frat	Subkutanju	200 µg ivermectin/kg bw, 5 mg closantel/kg bw

ANNESS II

KONKLUŻJONIJIET XJENTIFIČI U RAĠUNIJIET GHALL-EMENDA TAS-SOMMARJU TAL-KARATTERISTIČI TAL-PRODOTT, IT-TIKKETTA U L-FULJETT TA' TAGHRIF

SOMMARJU ĠENERALI TAL-EVALWAZZJONI XJENTIFIKA TA' PRODOTTI MEDICINALI VETERINARJI INJETTABBLI LI FIHOM IVERMECTIN

1. Introduzzjoni

Ivermectin huwa endectoicide ta' spettro wiesa' li ġej mill-familja ta' avermectin. Fil-każ tal-ifrat prodotti mediċinali injettabbli li fihom ivermectin, jew bħala sustanza attiva unika jew f'tahlita ma' sustanza attiva oħra, jintużaw kontra infestazzjonijiet minn endoparassiti u ektoparassiti billi jinghata 200 µg ivermectin/kg tal-piż tal-ġisem minn taht il-ġilda.

Ivermectin ġie evalwat minn qabel mis-CVMP sabiex jiġu stabbiliti l-limiti massimi ta' residwi (MRLs). Id-doża ta' kuljum tossikoloġikament aċċettabbli (ADI) ġiet stabbilita għal 10 µg/kg tal-piż tal-ġisem/jum (600 µg/persuna kuljum) ikkalkulata fuq il-bażi tan-NOEL ta' 0.5 mg/kg tal-piż tal-ġisem/kuljum miksub minn studju ta' 14-il ġimgħa fuq kelb, bl-applikazzjoni ta' fattur tas-sigurtà ta' 50.

Ivermectin fil-preżent huwa inkluż fl-Anness I tar-Regolament tal-Kunsill (KEE) Nru 2377/90 b'MRLs għall-ispeċi kollha li jipproduċu l-ikel kif ġej:

Sustanza farmakoloġikament attiva	Residwu markatur	Speċi tal-annimal	MRLs	Tessut fil-mira	Dispożizzjonijiet oħra
Ivermectin	22,23-Dihydro-avermectin B1a	L-ispeċi ta' mammiferi kollha tal-produttjoni tal-ikel	100 µg/kg 100 µg/kg 30 µg/kg	Xaħam Fwied Kliwi	Mhux għall-użu f'annimali li jipproduċu ħalib għall-konsum mill-bniedem.

Ibbażata fuq dawn il-MRLs, id-doża ta' kuljum tar-residwi totali tikkorrispondi għal madwar 15% tal-ADI.

Inghataw Awtorizzazzjonijiet għat-Tqeghid fis-Suq tal-prodotti mediċinali veterinarji injettabbli li fihom ivermectin għall-użu fl-ifrat fl-Istati Membri kollha tal-Unjoni Ewropea permezz ta' proċeduri ta' awtorizzazzjoni differenti (proċeduri ta' rikonoxximent reċiproku u proċeduri nazzjonali) u skont diversi bażijiet ġuridiċi (shiha, ġenerika, biblijografika, kunsens infurmat).

Ir-Renju Unit esprima t-thassib li d-differenza fil-perjodi ta' rtirar stabbiliti madwar l-Unjoni Ewropea għall-prodotti rilevanti tista' tippreżenta riskju serju potenzjali għas-saħħa tal-bniedem, u talab lill-Kumitat għall-Prodotti Mediċinali għall-Użu Veterinarju (CVMP) biex jagħti l-opinjoni tiegħu dwar din il-kwistjoni.

Il-proċedura kienet tinvolvi 293 prodott mediċinali veterinarju injettabbli awtorizzati li fihom ivermectin (ara Anness I).

2. Diskussjoni dwar kwistjonijiet speċifiċi mqajma fin-notifika ta' referenza

Mid-dejta globali sottomessa mid-detenturi tal-awtorizzazzjoni għat-tqeghid fis-suk (MAHs) u l-Awtoritajiet Kompetenti Nazzjonali tal-Istati Membri, 11-il studju biss tat-tnaqqis tar-residwi ta' ivermectin kienu kkunsidrati ta' kwalità adegwata għall-iskop ta' kalkolu tal-perjodi ta' rtirar, minhabba li kien f'dawn l-istudji biss li t-tessuti rilevanti li kienu jinkludu s-siti tal-injezzjoni ttiehdu kampjuni tagħhom u ġew analizzati. Ġie nnutat li xi whud mill-istudji kienu identiċi iżda ġew sottomessi minn MAHs differenti.

Kull fejn kien possibbli s-CVMP uża l-metodu statistiku għall-kalkolu tal-perjodi ta' rtirar individwali bbażat fuq studji uniċi, iżda skont in-Nota għall-Gwida tas-CVMP: approċċ lejn l-armonizzazzjoni tal-perjodi ta' rtirar (Note for Guidance: approach towards harmonisation of withdrawal periods, EMEA/CVMP/036/95)¹, fejn il-parametri meħtieġa ma dehrux li kienu validi għall-analiżi statistika, intuża l-approċċ alternattiv għall-kalkolu tal-perjodi ta' rtirar.

Minhabba li m'hemmx MRL tal-muskolu għall-ivermectin, intuża l-approċċ ibbażat fuq l-ADI għall-valutazzjoni tad-doża totali ta' kuljum ta' residwi li jistgħu jirriżultaw mill-konsum ta' tessuti ta' kull animal (EMA/CVMP/542/03-Final)².

Fil-każijiet li fihom intuża l-approċċ alternattiv għad-dejta tal-istudju dwar ir-residwu individwali, il-perjodu ta' rtirar ittiehed mill-ewwel punt ta' hin li fih id-dozi kollha kkalkulati kienu inqas mill-ADI, biż-żieda ta' perjodu ta' sigurtà. Intuża perjodu ta' sigurtà ta' 30% minhabba l-varjazzjoni kbira fil-valuri tad-doża, li kienet ikkawżata l-aktar mill-varjazzjoni ta' residwi misjuba fis-siti tal-injezzjoni.

Fuq il-bażi tal-11-il studju ta' tnaqqis tar-residwi ta' ivermectin ta' kwalità adegwata pprovduti, is-CVMP kkalkula l-perjodu ta' rtirar ta' 12-il prodott. Il-perjodi individwali ta' rtirar kkalkulati mis-CVMP varjaw minn 21 jum sa 78 jum. Barra minn hekk, għal 11-il prodott iehor li għalihom ġiet ipprovduta dejta dwar it-tnaqqis tar-residwi, ġie konkluż li ma setax ikun ikkalkulat perjodu ta' rtirar individwali minhabba li d-dejta speċifika għall-prodotti li ġiet sottomessa ma kinitx adegwata.

Mistoqsija ewlenija mqajma minn din ir-referenza ssaqsi jekk hemmx effett ta' formulazzjoni fuq it-tnaqqis tar-residwi mit-tessuti u b'mod partikolari mis-siti tal-injezzjoni. Biex jindirizzaw din il-mistoqsija l-esperti eżaminaw il-kompożizzjoni kwalitattiva u kwantitattiva tal-293 prodott li fihom ivermectin li huma suġġetti għal din ir-referenza, billi għabru flimkien il-prodotti li jistgħu jiġu kkunsidrati l-istess jew essenzjalment l-istess. B'dan il-mod, ġew stabbiliti 13-il grupp tal-formulazzjonijiet. Kull grupp kien fih prodotti kkunsidrati essenzjalment l-istess, fis-sens ta' formulazzjoni.

¹ Nota għall-gwida CVMP: Approċċ lejn l-armonizzazzjoni tal-perjodi ta' rtirar <http://www.emea.europa.eu/pdfs/vet/swp/003695en.pdf>

² Linja gwida tal-CVMP dwar ir-Residwi fis-Siti tal-Injezzjoni. Pubblikazzjoni fis-sit elettroniku tal-EMA, <http://www.emea.europa.eu/pdfs/vet/swp/054203en.pdf>

It-tabella ta' hawn taht turi l-lista tat-13-il grupp ta' formulazzjoni flimkien man-numru ta' prodotti f'kull grupp, in-numru ta' studji disponibbli għal kull grupp, u l-perjodi individwali ta' rtirar ikkalkulati għad-diversi prodotti li għalihom kien hemm disponibbli dejta adegwata. In-numerazzjoni tal-gruppi tal-formulazzjonijiet hija arbitrarja.

Tabella 1. Gruppi tal-formulazzjonijiet stabbiliti għall-293 prodott sugġetti għal din ir-referenza.

Grupp ta' formulazzjoni	Numru ta' prodotti	Numru ta' studji aċċettabbli dwar it-tnaqqis tar-residwi	Perjodi individwali ta' rtirar (f'jiem) li rriżultaw mill-istudji tar-residwi ta' ivermectin
1	108	5	21, 23, 37, 47, >49
2	45	1	46
3	18	1	42
4	58	1	29
5	3	L-ebda dejta adatta	–
6	22	1	78
7	1	L-ebda dejta adatta	–
8	1	L-ebda dejta adatta	–
9	2	L-ebda dejta adatta	–
10	19	1	55
11	13	1	29
12	2	L-ebda dejta adatta	–
13	1	L-ebda dejta adatta	–

Mit-tabella 1 ta' hawn fuq, huwa ċar li għall-grupp 1, li għalih kienu disponibbli għadd ta' studji, il-firxa tal-perjodi ta' rtirar ikkalkulati kienet tvarja b'mod konsiderevoli (minn 21 sa >49 jum). Il-varjabilità fil-perjodi ta' rtirar ikkalkulati tirrifletti l-varjabilità fil-profilu tat-tnaqqis u b'mod partikolari l-varjabilità fit-tnaqqis tar-residwi mis-sit tal-injezzjoni. Ta' min jinnota li għall-parti l-kbira tal-istudji t-tixrid tad-dejta kien tali li ma setax jintuża l-metodu statistiku armonizzat għall-istabbiliment tal-perjodi ta' rtirar, u l-perjodu ta' rtirar li jirriżulta mill-użu tal-metodu alternattiv dejjem jiddependi hafna fuq l-għażla tal-punti ta' hin.

Sar tentattiv biex tinstab korrelazzjoni bejn koeffiċjenti angolari (*slopes*) jew interċetti (*intercepts*) tal-kurvi tat-tnaqqis u kwalunkwe wiehed mill-parametri li ġejjin: grupp ta' formulazzjoni, piż tal-ġisem, razza, sess, età, u volum injettat bl-użu tal-metodoloġija ANOVA jew ta' Pearson. Mid-dejta disponibbli ma nstabu l-ebda korrelazzjonijiet li setgħu jispjegaw id-differenza fil-profilu tat-tnaqqis jew fil-perjodi stmati ta' rtirar, u l-ebda wiehed mill-parametri rreġistrati ma seta' jiġi identifikat bħala sors uniku kbir ta' varjazzjoni.

Għalkemm is-sorsi eżatti ta' varjazzjoni jibqgħu mhux identifikati, huwa probabbli li l-proċedura tat-tehid tal-kampjuni hija fattur wiehed importanti; huwa diffiċli li wiehed ikun żgur li l-parti bl-ogħla konċentrazzjoni ta' residwi tigi ttestjata bir-reqqa, b'mod partikolari għall-injezzjonijiet subkutanji. Il-livell għoli ta' varjazzjoni fil-konċentrazzjonijiet ta' residwi u fil-profilu tat-tnaqqis li deher kemm fil-gruppi ta' formulazzjoni kif ukoll bejniethom seta' faċilment heba l-effett ta' formulazzjoni. Kumplessivament, mid-dejta analizzata, il-preżenza ta' effett ta' formulazzjoni la tista' tigi kkonfermata u lanqas miċhuda. Għalhekk sorsi oħra ta' varjazzjoni marbutin mal-użu subkutanju ta' ivermectin tqiesu aktar importanti mill-formulazzjoni fir-rigward tat-tnaqqis tar-residwi u l-perjodi ta' rtirar.

Madankollu, id-dejta mil-letteratura tindika li l-formulazzjoni jista' jkollha impatt fuq ir-rata ta' assorbiment tal-ivermectins mis-siti tal-injezzjoni. Effett bħal dan deher f' studji sperimentali magħmula min-numru ta' gruppi differenti (Lo *et al.*, 1985³; Wicks *et al.*, 1993⁴; Lifschitz *et al.* 1999⁵, Lifschitz *et al.*, 2004⁶). F'dawn l-istudji, formulazzjonijiet differenti wrew stili differenti ta' assorbiment tal-ivermectins (inkluż ivermectin), filwaqt li l-parametri l-oħra kollha kienu l-istess (bħalma huma l-ispeċi, ir-razza, il-piż, u s-sit tal-injezzjoni). Dawn l-osservazzjonijiet jappoġġjaw l-opinjoni li fl-istudji pprovduti lill-CVMP, kien hemm sorsi ta' varjazzjoni li kienu aktar importanti mill-effetti tal-formulazzjoni.

Bħala kwistjoni ta' prinċipju fir-rigward ta' prodotti li ntwerew li huma bijoekwivalenti, ta' min jinnota li d-definizzjoni ta' bijoekwivalenza ma tiggarantixxi livelli ugwali ta' residwi fis-sit tal-injezzjoni lil hinn hafna mill-hin ta' meta ttiehdu kampjuni tal-plażma. Fil-fatt, differenza żgħira u farmakoloġikament insinifikanti fil-frazzjoni assorbita (eż. 99.5% kontra 99.9%) f'ċertu punt ta' hin tista' timplika differenza sinifikanti fl-ammont li jifdal fis-sit tal-injezzjoni (f'dan l-eżempju fattur ta' 5).

³ Lo, P.-K.A., Fink, D.W., Williams, J.B., Blondinger, J. (1985) Pharmacokinetic studies of ivermectin: effects of formulation. *Vet. Res. Comm.* **9**: 251-268

⁴ Wicks, S.R., Kaye, B., Weatherley, A.J., Lewis, D., Davison, E., Gibson, S.P., Smith, D.G. (1993) Effect of formulation on the pharmacokinetics and efficacy of doramectin. *Vet. Parasitol.* **49**: 17-26

⁵ Lifschitz, A., Virkel, G. Pis, A., Imperiale, F., Sanchez, S., Alvarez, L., Kujanek, R., Lanusse, C. (1999) Ivermectin disposition kinetics after subcutaneous and intramuscular administration of an oil-based formulation to cattle. *Vet. Parasitol.* **86**: 203-215

⁶ Lifschitz, A., Sallovitz, J., Imperiale, F., Pis, A., Jauregui Lorda, J., Lanusse, C. (2004) Pharmacokinetic evaluation of four ivermectin generic formulations in calves. *Vet. Parasitol.* **119**: 247-257

Minhabba li l-ekwivalenza tal-livelli tar-residwi lokali fis-sit tal-injezzjoni ma tistax tiġi mbassra fuq bażi tal-bijoeqwivalenza tal-plażma, u minhabba li dejta stampata tindika li l-formulazzjoni jista' jkollha impatt fuq il-profil tat-tnaqqis tar-residwi għal ivermectin, il-CVMP qies li, b'mod ġenerali, m'hemmx bażi għall-estrapolazzjoni awtomatika ta' perjodu ta' rtirar stabbilit għal formulazzjoni waħda fuq formulazzjoni oħra, anki jekk tkun intweriet bijoeqwivalenza tal-plażma.

Min-naħa l-oħra, m'hemm l-ebda raġuni xjentifika li tispjega għalfejn il-perjodi ta' rtirar għall-formulazzjonijiet li huma l-istess jew essenzjalment l-istess, għandhom ikunu differenti. Għalkemm id-dejta analizzata mis-CVMP wasslet fil-fatt għall-kalkolu ta' perjodi ta' tnaqqis differenti għal prodotti li huma essenzjalment l-istess, din il-varjabilità mhix ikkunsidrata li tirrifletti effetti speċifiċi tal-prodott iżda hija pjuttost karatteristika tal-mod kif intużaw il-prodotti (jiġifieri l-varjazzjoni tirriżulta minn differenzi bħalma huma l-piż tal-ġisem tal-annimal, ir-razza, is-sess, l-età, il-volum ta' injezzjoni u l-proċedura tal-ittestjar).

Is-CVMP jikkunsidra li prodotti li huma essenzjalment l-istess (fis-sens ta' formulazzjoni) għandu jkollhom perjodi ta' rtirar identiċi. Għall-finijiet ta' din ir-referenza, dan ifisser li l-perjodi ta' rtirar għall-prodotti kollha fl-istess grupp ta' formulazzjonijiet għandhom ikunu ugwali. Barra minn hekk, minhabba l-fatt li l-varjazzjoni fil-profil tar-residwi dovuta għal sorsi ta' varjazzjoni marbuta mal-użu subkutanju ta' ivermectin hija hafna akbar mill-effett ta' formulazzjoni, il-Kumitat ikkonkluda li jkun xieraq li tiġi kkunsidrata d-dejta kollha tar-residwi ta' ivermectin mill-gruppi ta' formulazzjonijiet kollha biex jinhareġ perjodu ta' rtirar wiehed armonizzat.

2.1 Kalkolu ta' perjodu ta' rtirar armonizzat għall-prodotti injettabbli li fihom ivermectin għall-użu fl-ifrat

Fil-figura ta' hawn taht, id-dejta kollha disponibbli għad-doża totali ta' residwi ta' ivermectin hija ppreżentata fi grafiku u mqabbla mal-ADI.

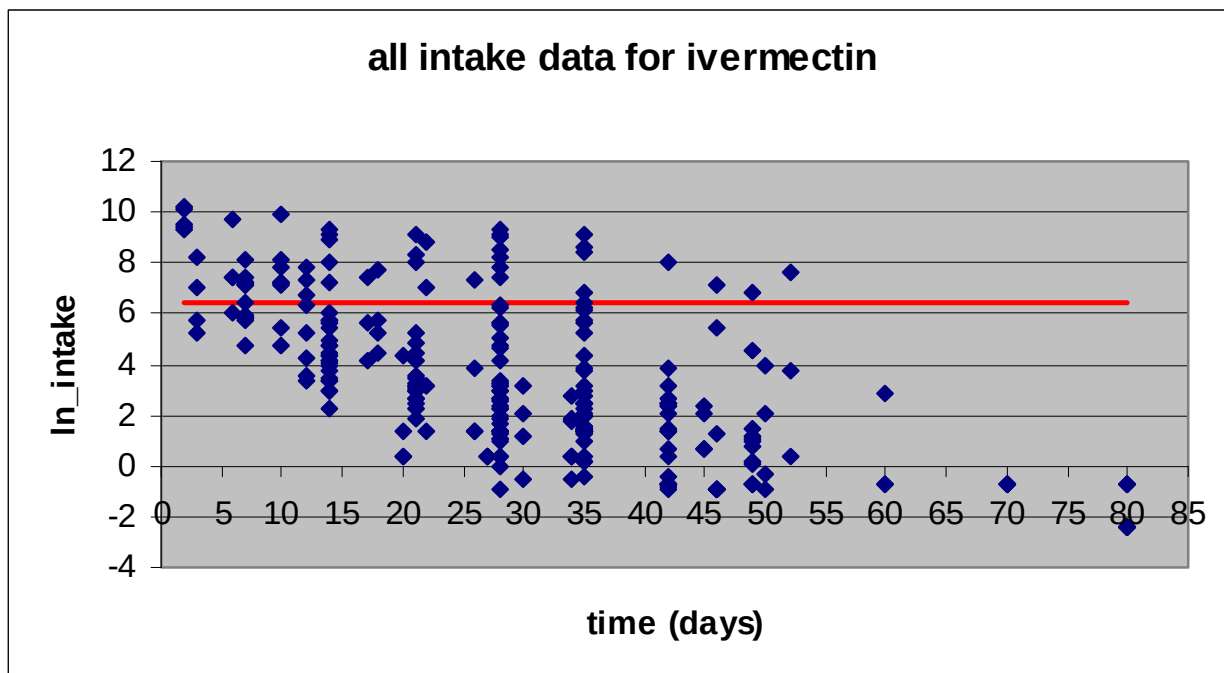


Figura 1. Fuq skala logaritmika, id-doża kumplessiva ta' residwi ta' ivermectin (μg) ta' konsumatur, ikkalkulata minn dejta ta' kull animal (punti ta' dejta), imqabbla mal-ADI ($\mu\text{g}/\text{persuna}$, linja orizzontali).

Ma kienx possibbli li jintuza l-metodu statistiku għall-analizi ta' din id-dejta miġbura minhabba li ma ntlahqax għadd ta' ipoteżijiet statistikament rilevanti. Madankollu, il-Kumitat ikkunsidra li l-użu tal-approċċ alternattiv (l-ewwel punt ta' hin taht l-ADI flimkien maż-żmien ta' sigurtà) ma jqisx biżżejjed l-ammont sostanzjali ta' dejta (280 punt ta' dejta) disponibbli f'dan il-każ partikolari. Il-Kumitat ikkunsidra li fuq il-bażi tad-dejta kollha, u fuq il-bażi tal-fatt li fid-49 jum u wara l-kalkolu tad-doża jibqa' 'l fuq mill-ADI għal żewġ annimali biss, perjodu ta' rtirar ta' 49 jum għandu jipprovdi grad ta' sigurtà komparabbli ma' dak pprovdut permezz tal-metodu statistiku (u perjodu ta' rtirar ibbażat fuq il-limitu ta' tolleranza ta' 95%). Għaldaqstant, il-Kumitat ikkonkluda li perjodu ta' rtirar armonizzat ta' 49 jum jista' jiġi stabbilit għall-komponent ivermectin tal-prodotti injettabbli kollha li fihom ivermectin, għall-użu fl-ifrat.

2.2 Derivazzjoni tal-perjodu ta' rtirar għal prodotti mediċinali veterinarji injettabbli li fihom ivermectin flimkien ma' sustanza attiva oħra (prodotti kkumbinati)

Il-perjodu ta' rtirar armonizzat ta' 49 jum huwa rilevanti biss għall-komponent ivermectin ta' prodotti injettabbli li fihom ivermectin. Għal prodotti mediċinali veterinarji injettabbli li fihom ivermectin flimkien ma' sustanza attiva oħra it-tnaqqis ta' residwi tat-tieni sustanza attiva għandu jkun ikkunsidrat ukoll, u għandu jkun stabbilit perjodu ta' rtirar għat-tieni sustanza attiva. Il-perjodu ta' rtirar għall-prodott għandu jkun l-itwal perjodu ta' rtirar li jirriżulta għall-komponenti individwali. Jekk il-perjodu ta' rtirar ikkalkulat fuq il-bażi tad-dejta tat-tnaqqis tar-residwi għat-tieni sustanza attiva jkun inqas minn 49 jum, allura huwa rrakkomandat perjodu ta' rtirar ta' 49 jum għall-prodott. Jekk, min-naħa l-oħra, il-perjodu ta' rtirar ikkalkulat fuq il-bażi tad-dejta tat-tnaqqis tar-residwi għat-tieni sustanza attiva jkun itwal minn 49 jum, allura l-perjodu ta' rtirar irrakkomandat għall-prodott għandu jkun ibbażat fuq it-tnaqqis tar-residwi tat-tieni sustanza attiva. Għaldaqstant, perjodu ta' rtirar ta' mill-inqas 49 jum għandu japplika għall-prodotti kkumbinati f'kull każ.

Mill-gruppi tal-formulazzjonijiet li għalihom ġew allokat i-prodotti f'din il-proċedura, tnejn kien fihom prodotti kkumbinati, wiehed bi prodotti li kien fihom is-sustanzi attivi ivermectin u clorsulon, u l-ieħor bi prodotti li kien fihom is-sustanzi attivi ivermectin u closantel.

Il-prodotti kollha li kien fihom ivermectin u clorsulon kellhom formulazzjonijiet simili u ġew ipprezentati għadd ta' studji dwar it-tnaqqis tar-residwi għall-komponent clorsulon tal-prodotti f'dan il-grupp. L-istudji saru kif xieraq u kienu jinkludu numru konsiderevoli ta' punti ta' ħin tal-qatla. Meta wiehed iqis it-totalità tad-dejta dwar it-tnaqqis tar-residwi ta' clorsulon, il-metodu statistiku ma setax jintuza għall-kalkolu tal-perjodi ta' rtirar minhabba li l-ipoteżijiet statistiċi rilevanti ma ġewx issodisfati. Meta wiehed jikkunsidra d-dejta ta' residwi tal-istudji, l-ewwel punt ta' żmien li fih l-ebda valur ma qabeż l-MRL għal clorsulon kien 60 jum. Bl-użu tal-approċċ alternattiv u bl-applikazzjoni ta' perjodu ta' sigurtà ta' 10% irriżulta perjodu ta' rtirar ta' 66 jum. Perjodu ta' sigurtà ta' 10% kien meqjus xieraq minhabba li l-istudji kienu vasti u b'saħħithom.

Minhabba li l-perjodu ta' rtirar ikkalkulat, ibbażat fuq il-komponent clorsulon għal dawn il-prodotti, jaqbeż id-49 jum ikkalkulat għall-komponent ivermectin, huwa rrakkomandat perjodu ta' rtirar ta' 66 jum għall-prodotti kkumbinati li fihom ivermectin u clorsulon.

Id-dejta dwar it-tnaqqis tar-residwi sottomessa għall-grupp ta' formulazzjonijiet li fihom ivermectin u closantel wasslet għal perjodu ta' rtirar ta' 36 jum għal closantel, ikkalkulat bl-użu tal-approċċ alternattiv u bl-applikazzjoni ta' perjodu ta' sigurtà ta' 30%. Minhabba li dan huwa taħt il-limitu ta' 49 jum applikat għall-komponent ivermectin, huwa rrakkomandat perjodu ta' rtirar ta' 49 jum għall-prodotti kkumbinati li fihom ivermectin u closantel.

RAĠUNIJIET GHALL-EMENDA TAS-SOMMARJU TAL-KARATTERISTIČI TAL-PRODOTT

Billi:

- is-CVMP evalwa d-dejta oriġinali pprovduta matul din ir-referenza u kkonkluda li, fuq il-bażi ta' din id-dejta, ma setax jintwera l-impatt tal-formulazzjoni fuq it-tnaqqis tar-residwi u li l-varjabilità fid-dejta kienet tali li effett ta' formulazzjoni fuq it-tnaqqis tar-residwi seta' gie mohbi;
- is-CVMP kkunsidra li hemm preżenti sorsi ta' varjazzjoni marbuta mal-użu subkutanju ta' ivermectin fl-ifrat li jistgħu jwasslu għal profili ta' tnaqqis differenti fi studji tar-residwi, u din il-varjazzjoni hija hafna aktar importanti minn kwalunkwe varjazzjoni li tista' tigi kkawżata minn differenzi ta' formulazzjoni. Dawn id-differenzi huma mistennija li jseħħu wkoll fil-prattika;
- is-CVMP kkunsidra, meta wiehed iqis il-varjazzjoni kbira osservata, għandu jiġi stabbilit perjodu ta' rtirar uniku armonizzat ibbażat fuq id-dejta kollha disponibbli dwar it-teħid ta' residwi għall-prodotti kollha kkonċernati li fihom ivermectin bħala l-unika sustanza attiva;
- is-CVMP kkunsidra li għal prodotti kkumbinati li fihom ivermectin flimkien ma' sustanza attiva oħra, it-tnaqqis tar-residwi tat-tieni sustanza attiva għandu jkun ikkunsidrat ukoll meta jkun qed jiġi stabbilit il-perjodu ta' rtirar u l-perjodu ta' rtirar għall-prodott għandu jkun l-itwal wiehed stabbilit għall-komponenti individwali.

is-CVMP irrakkomanda l-emenda tal-Awtorizzazzjonijiet għat-Tqeghid fis-Suq għall-prodotti mediċinali veterinarji injettabbli kollha li fihom ivermectin għall-użu fl-ifrat kif imsemmija fl-Anness I li għalihom, is-Sommarju tal-Karatteristiċi tal-Prodott, it-tikketta u l-fuljett ta' tagħrif huma stabbiliti fl-Anness III.

ANNESS III

**EMENDA GHAS-SOMMARJU TAL-KARATTERISTIČI TAL-PRODOTT, IT-
TIKKETTA U L-FULJETT TA' TAGHRIF**

**EMENDI LI GHANDHOM JIĠU INKLUŻI FIS-SEZZJONIJIET RILEVANTI TAS-
SOMMARJU TAL-KARATTERISTIĊI TAL-PRODOTT**

A. Għall-prodotti elenkati fl-Anness I li fihom ivermectin u clorsulon bħala sustanzi attivi:

4.11 Perjodu/i ta' Rtirar

Frat: Laħam u ġewwieni - 66 jum

B. Għall-prodotti elenkati fl-Anness I li fihom ivermectin bħala l-unika sustanza attiva jew flimkien ma' closantel:

4.11 Perjodu/i ta' Rtirar

Frat: Laħam u ġewwieni - 49 jum

**EMENDI LI GHANDHOM JIĠU INKLUŻI FIS-SEZZJONIJIET RILEVANTI TAT-
TIKKETTA**

A. Għall-prodotti elenkati fl-Anness I li fihom ivermectin u clorsulon bħala sustanzi attivi:

8. PERJODU TA' RTIRAR

Frat: Laħam u ġewwieni - 66 jum.

B. Għall-prodotti elenkati fl-Anness I li fihom ivermectin bħala l-unika sustanza attiva jew flimkien ma' closantel:

8. PERJODU TA' RTIRAR

Frat: Laħam u ġewwieni - 49 jum.

**EMENDI LI GHANDHOM JIĠU INKLUŻI FIS-SEZZJONIJIET RILEVANTI TAL-
FULJETT TA' TAGHRIF**

A. Għall-prodotti elenkati fl-Anness I li fihom ivermectin u clorsulon bħala sustanzi attivi:

10. PERJODU TA' RTIRAR

Frat: Laham u ġewwieni - 66 jum.

B. Għall-prodotti elenkati fl-Anness I li fihom ivermectin bħala l-unika sustanza attiva jew flimkien ma' closantel:

10. PERJODU TA' RTIRAR

Frat: Laham u ġewwieni - 49 jum