



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2022
EMA/780567/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): itraconazole

Procedure No. PSUSA/00001798/202203



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
Sporanox 10 mg/ml Lösung zum Einnehmen	IE/H/0838/001	1-22084	JANSSEN-CILAG PHARMA GMBH	AT
Sporanox DERM 100 mg Kapseln	not available	1-20781	JANSSEN-CILAG PHARMA GMBH	AT
Sporanox 100 mg Kapseln	not available	1-19236	JANSSEN-CILAG PHARMA GMBH	AT
Mytra 50 mg Hartkapseln	UK/H/4345/001	137209	A-MED GMBH	AT
SPORANOX 10 mg/ml, drank.	IE/H/0838/001	BE190294	JANSSEN-CILAG NV	BE
SPORANOX 100 mg, capsules, hard	not available	BE 145905	JANSSEN-CILAG NV	BE
SPORAL™ 100 mg Capsules, hard.	not available	12662	JANSSEN-CILAG INTERNATIONAL NV	CY
SPORANOX 10 mg/ml perorální roztok	not available	26/1097/97-C	JANSSEN-CILAG S.R.O	CZ
Sempera Liquid 10 mg/ml, Lösung zum Einnehmen	IE/H/0838/001	39682.00.00	JANSSEN-CILAG GMBH	DE
ITRAISDIN 50 mg Hartkapseln	ES/H/0599/001/DC	83943.00.00	ISDIN GMBH	DE
SEMPERA Kapseln 100 mg Hartkapseln	not available	31040.00.00	JANSSEN-CILAG GMBH	DE
Sporanox, kapsler	not available	13777	JANSSEN-CILAG A/S	DK
Itragerm 50 mg cápsulas duras	ES/H/0599/001	77459	ISDIN, S.A.	ES
CANADIOL 100 mg cápsulas	not available	59.371	ESTEVE PHARMACEUTICALS, S.A.	ES
SPORANOX 100 mg cápsulas	not available	59.343	JANSSEN-CILAG S.A.	ES
Hongoseril 100 mg cápsulas	not available	59.591	ISDIN, S.A.	ES
SPORANOX 10 mg/ml oraalliluios	IE/H/0838/001	12546	JANSSEN-CILAG OY	FI
Sporanox 100 mg kapseli, kova	not available	11191	JANSSEN-CILAG OY	FI
SPORANOX 100 mg, gélule	not available	34009 334 602 9 7	JANSSEN-CILAG	FR
SPORANOX 100 mg, gélule	not available	34009 334 603 5 8	JANSSEN-CILAG	FR
SPORANOX 100 mg, gélule	not available	34009 334 604 1 9	JANSSEN-CILAG	FR
SPORANOX 100 mg, gélule	not available	34009 334 627 1 0	JANSSEN-CILAG	FR
SPORANOX 100 mg, gélule	not available	34009 334 628 8 8	JANSSEN-CILAG	FR
SPORANOX 100 mg, gélule	not available	34009 334 630 2 1	JANSSEN-CILAG	FR
SPORANOX 10 mg/ml, solution	not available	34009 345 020 6 4	JANSSEN-CILAG	FR

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
buvable				
SPORANOX 100 mg, gélule	not available	34009 557 937 0 0	JANSSEN-CILAG	FR
SPORANOX 100 MG καψάκια σκληρά	not available	66994/04.12.2018	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
SPORANOX 10 mg/mL Oral Solution	IE/H/0838/001/MR001	PA 22612/012/001	JANSSEN SCIENCES IRELAND UC	IE
Sporanox 100 mg hörð hylki.	not available	920150	JANSSEN-CILAG AB	IS
SPORANOX 10 mg/ml soluzione orale	IE/H/0838/001	027808029/M	JANSSEN-CILAG SPA	IT
TRIASPORIN 10 mg/ml soluzione orale	not available	027814021	ITALFARMACO S.P.A	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757019	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757021	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757033	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757045	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757058	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757072	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757084	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757096	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757108	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757110	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757122	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757134	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757146	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757159	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757161	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757173	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757185	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757197	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757060	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757209	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757211	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757223	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757235	ISDIN S.R.L.	IT
Itragerm 50 mg capsule rigide	ES/H/0599/001	044757247	ISDIN S.R.L.	IT
SPORANOX 100 mg capsule rigide	not available	027808017	JANSSEN-CILAG SPA	IT
TRIASPORIN 100 mg capsule	not available	027814019	ITALFARMACO 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
rigide				
SPORANOX 10 mg/ml solution buvable.	IE/H/0838/001	2002016306	JANSSEN-CILAG NV	LU
Sporanox 100 mg, gélules	not available	2008089906	JANSSEN-CILAG NV	LU
Trisporal O.S.-drank 10 mg/ml, drank.	IE/H/0838/001	RVG 21024	JANSSEN-CILAG BV	NL
Sporanox 100 mg kapsel, hard	not available	8158	JANSSEN-CILAG A/S	NO
Orungal, 100 mg, kapsułki	not available	R/0043	JANSSEN-CILAG INTERNATIONAL NV	PL
SPORANOX 10 mg/ml Solução Oral	IE/H/0838/001	2588382	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Itragerm 50 mg cápsulas.	ES/H/0599/001	5740410	ISDIN LDA	PT
Itragerm 50 mg cápsulas.	ES/H/0599/001	5740428	ISDIN LDA	PT
Itragerm 50 mg cápsulas.	ES/H/0599/001	5740436	ISDIN LDA	PT
Itragerm 50 mg cápsulas.	ES/H/0599/001	5740360	ISDIN LDA	PT
Itragerm 50 mg cápsulas.	ES/H/0599/001	5740378	ISDIN LDA	PT
Itragerm 50 mg cápsulas.	ES/H/0599/001	5740402	ISDIN LDA	PT
Sporanox 100 mg cápsulas	not available	8722330	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Sporanox 100 mg cápsulas	not available	8722322	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Sporanox 100 mg cápsulas	not available	8722306	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Sporanox 100 mg cápsulas	not available	8722314	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Micogal 100 mg capsule	not available	7080/2014/01	S.C. ROMPHARM COMPANY S.R.L.	RO
Orungal 100 mg capsule	not available	11593/2019/01	JANSSEN PHARMACEUTICA NV	RO
Orungal 100 mg capsule	not available	11593/2019/02	JANSSEN PHARMACEUTICA NV	RO
Orungal 100 mg capsule	not available	11593/2019/03	JANSSEN PHARMACEUTICA NV	RO
Sporanox 10 mg/ml oral lösning	IE/H/0838/001	13358	JANSSEN-CILAG AB	SE
Sporanox 100 mg hårda kapslar	not available	11900	JANSSEN-CILAG AB	SE
Sporanox 100 mg trde kapsule	not available	H/92/01453/003	JOHNSON & JOHNSON D.O.O.	SI

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
SPORANOX 100 mg kapsuly	not available	26/0194/90-C/S	JOHNSON & JOHNSON, S.R.O	SK
SPORANOX 10 mg/ml Oral Solution.	IE/H/0838/001	PL 00242/0307	JANSSEN-CILAG LIMITED	XI
Sporanox 100 mg Capsules	not available	PL 00242/0142	JANSSEN-CILAG LIMITED	XI