AIFA – Agenzia Italiana del Farmaco

EMA raccomanda la sospensione per i medicinali i cui studi di bioequivalenza sono stati condotti presso il sito Semler Research Center – Bangalore – India

22 Luglio 2016

L'Agenzia Europea dei Medicinali (EMA) ha raccomandato la sospensione nell'UE di tutti i farmaci approvati o in via di approvazione i cui studi di bioequivalenza (di norma presenti nel dossier della domanda di autorizzazione di un medicinale equivalente), siano stati condotti da parte dell'Organizzazione di Ricerca a Contratto (CRO) Semler Research Centre Private Ltd, situata a Bangalore, in India. Per l'Italia si tratta di due sole specialità medicinali attualmente in commercio. L'AIFA ha deciso in via cautelativa di avviare le procedure di sospensione nel nostro Paese. Non vi è al momento alcuna evidenza di effetti dannosi o di mancanza di efficacia dei farmaci interessati, per i quali sono comunque disponibili valide alternative terapeutiche.

L'EMA ha condotto una revisione a seguito di quanto emerso da due diverse ispezioni dei siti bioanalitici e clinici della CRO indiana condotte prima dalla Food and Drug Administration e successivamente dall'Organizzazione Mondiale della Sanità, che hanno rilevato irregolarità del sistema di gestione della qualità della Semler, relative fra le altre alla manipolazione e all'integrità dei campioni utilizzati per gli studi clinici.

La revisione della Semler è stata effettuata dal Comitato per i medicinali per uso umano (CHMP) dell'EMA a partire dallo scorso 28 aprile su richiesta della Danimarca, Germania, Paesi Bassi, Spagna e Regno Unito ai sensi dell'articolo 31 della direttiva 2001/83 / CE.

Il CHMP ha dichiarato la non ammissibilità degli studi condotti presso la Semler e pertanto le richieste di autorizzazione all'immissione in commercio nell'UE dei farmaci basati su questi studi non possono ottenere alcuna approvazione.

Nessun medicinale generico autorizzato con *procedura centralizzata* dall'EMA è stato valutato nel sito Semler Research Center – Bangalore.

La raccomandazione del CHMP sarà ora inviata alla Commissione Europea per una decisione giuridicamente vincolante valida in tutta l'UE.

Leggi il comunicato sul sito dell'EMA

22 July 2016
EMA/489380/2016

EMA recommends suspension of medicines over flawed studies at Semler Research Centre

Bioequivalence studies performed at the site cannot be used to support medicines approval in the EU

The European Medicines Agency (EMA) has recommended suspending a number of nationally approved medicines for which bioequivalence studies were conducted at Semler Research Centre Private Ltd, Bangalore, India. The Agency has also recommended that medicines currently being evaluated for authorisation and which rely only on bioequivalence studies from this site should not be authorised until bioequivalence is demonstrated using alternative data. Bioequivalence studies usually form the basis for approval of generic medicines.

The list of medicines recommended for suspension can be found here.

EMA's review followed an FDA inspection[1] that identified several issues at Semler's bioanalytical site, including the substitution and manipulation of subjects' clinical samples. The World Health Organization (WHO) also raised serious concerns[2] regarding data integrity and manipulation of study samples following its own inspections of Semler's bioanalytical and clinical sites.

The findings from FDA and WHO inspections call into question the quality management system in place at Semler, and thus on the reliability of the data of all bioequivalence studies, including those used to support marketing authorisation applications in the EU. EMA's Committee for Medicinal Products for Human Use (CHMP) has concluded that the studies conducted at Semler cannot be accepted in marketing authorisation applications in the EU. Thus, no medicines can be approved on the basis of these studies.

During the evaluation, alternative studies were provided for some of these medicines. These studies show bioequivalence, and therefore, the CHMP has recommended that these medicines can remain on the market. The list of medicines recommended to remain on the market can be found here.

Some of the medicines which have been recommended for suspension may be of critical importance (e.g. due to lack of available alternatives) in a given EU Member State. Therefore national authorities can temporarily postpone the suspension in the interest of patients. Member States should also decide whether recalls of the affected medicines are needed in their territories.

[1] http://www.fda.gov/Drugs/DrugSafety/ucm495778.htm

[2] http://apps.who.int/prequal/info_applicants/NOC/2016/NOC_Semler12April2016.pdf

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The CHMP's recommendation concerning these medicines will now be sent to the European Commission for a legally binding decision valid throughout the EU.

Information for patients and healthcare professionals

- A number of medicines for use in the EU rely on studies carried out at the Semler site in India. The studies, called 'bioequivalence' studies, are usually the basis for approving generic medicines.
- The bioequivalence studies performed at the Semler site have been found to be flawed, so they cannot be relied on. As a result, several medicines approved in the EU are being suspended.
- The list of medicines recommended for suspension can be found here.
- National authorities in the EU will consider how critical individual medicines are in their countries and make final decisions on whether to suspend or allow them to remain available, while new data are generated.
- There is currently no evidence of unexpected harm or lack of effectiveness with any medicine approved on the basis of studies conducted at Semler.
- Generic medicines containing abacavir/lamivudine (used to treat HIV), which were approved on the basis of studies conducted at Semler, can remain on the market in the EU. This is because during this review, alternative studies from different sources were provided that show bioequivalence.
- Medicines still under evaluation cannot be granted authorisation in the EU on the basis of studies conducted at Semler; further data would have to be provided to support authorisation.
- Medicines to be suspended can have their suspension lifted if the companies provide alternative data demonstrating bioequivalence.
- Patients should continue to take their medicines as prescribed and contact their doctors in case of questions or concerns.

More about the medicines covered by this review

The review covers medicines authorised via national procedures in individual EU Member States, whose marketing authorisation applications included data from Semler's bioanalytical site (Semler Research Center Private Ltd, 75A, 15th Cross, 1st Phase, JP Nagar, Bangalore 560 078, Karnataka, India) and from Semler's clinical site (PA Arcade, #21, 22, 23, Kodigehali Main Road, Sahakaranagar Post, Bangalore 560 092, Karnataka, India).

It also includes ongoing marketing authorisation applications for medicines which use study data from these sites. No generic medicine authorised centrally via EMA was tested in these sites.

More about Semler

Semler is a contract research organisation (CRO) with an analytical and a clinical site located in Bangalore, India. These sites conduct the analytical and clinical parts of bioequivalence studies, some of which are used to support marketing authorisation applications of medicines in the EU. The Semler

site also performs bioequivalence studies for some medicines authorised in the US and medicines included in the WHO prequalification programme[3].

More about the procedure

The review of Semler was initiated on 28 April 2016 at the request of Denmark, Germany, the Netherlands, Spain and the United Kingdom under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's opinion. The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

The CHMP opinion allows for national authorities to take decisions on how critical individual medicines are in their countries.

Contact our press officer

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[3] http://www.who.int/prequal

22 July 2016
EMA/499744/2016
Procedure Management and Business Support

Marketing authorisations which are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation as adopted by the CHMP on 21 July 2016

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1443

Some of these medicinal products may be considered critical by the individual EU Member States. The suspension of the concerned marketing authorisation(s) may be deferred by the period for which the medicinal product is considered critical.

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Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Belgium		Sandoz NV	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Belgium		Sandoz NV	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Belgium		Sandoz NV	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Belgium		Teva Pharma Belgium NV	Erlotinib Ratiopharm	erlotinib	25 mg	Film-coated tablet	Oral use
Belgium		Teva Pharma Belgium NV	Erlotinib Ratiopharm	erlotinib	100 mg	Film-coated tablet	Oral use
Belgium		Teva Pharma Belgium NV	Erlotinib Ratiopharm	erlotinib	150 mg	Film-coated tablet	Oral use
Belgium		Accord Healthcare Ltd	Saquinavir Accord	saquinavir	500 mg	Film-coated tablet	Oral use
Belgium	Teva Pharma Belgium NV		Atovaquone/Proguanil Teva	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Belgium	Teva Pharma Belgium NV		Atovaquone/Proguanil Teva	atovaquone/ proguanil	250 mg/ 100 mg	Film-coated tablet	Oral use
Belgium	Sandoz NV		Malaprotec	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Belgium	Sandoz NV		Malaprotec	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Belgium	Sandoz NV		Saquinavir Sandoz	saquinavir	500 mg	Film-coated tablet	Oral use
Bulgaria		Teva B.V.	Erlotinib Teva Pharma B.V	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Bulgaria		Teva B.V.	Erlotinib Teva Pharma B.V	erlotinib	150 mg	Film-coated tablet	Oral use
Bulgaria		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Bulgaria		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Bulgaria		Accord Healthcare Limited	Saquinavir Accord	saquinavir	500 mg	Film-coated tablet	Oral use
Croatia		Sandoz B.V.	Erlotinib Sandoz 25 mg filmom obložene tablete	erlotinib	25 mg	Film-coated tablet	Oral use
Croatia		Sandoz B.V.	Erlotinib Sandoz 100 mg filmom obložene tablete	erlotinib	100 mg	Film-coated tablet	Oral use
Croatia		Sandoz B.V.	Erlotinib Sandoz 150 mg filmom obložene tablete	erlotinib	150 mg	Film-coated tablet	Oral use
Croatia		Teva B.V.	Erlotinib Pliva Hrvatska 25 mg filmom obložene tablete	erlotinib	25 mg	Film-coated tablet	Oral use
Croatia		Teva B.V.	Erlotinib Pliva Hrvatska 100 mg filmom obložene tablete	erlotinib	100 mg	Film-coated tablet	Oral use
Croatia		Teva B.V.	Erlotinib Pliva Hrvatska 150 mg filmom obložene tablete	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Croatia		Edicta Pharm d.o.o.	Edinib 25 mg filmom obložene tablete	erlotinib	25 mg	Film-coated tablet	Oral use
Croatia		Edicta Pharm d.o.o.	Edinib 100 mg filmom obložene tablete	erlotinib	100 mg	Film-coated tablet	Oral use
Croatia		Edicta Pharm d.o.o.	Edinib 150 mg filmom obložene tablete	erlotinib	150 mg	Film-coated tablet	Oral use
Cyprus		Sandoz B.V.	Erlotinib Hydrochloride Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Cyprus		Accord Healthcare Ltd	Saquinavir Accord	saquinavir	500 mg	Film-coated tablet	Oral use
Czech Republic		Sandoz B.V.	Erlotinib Sandoz 25 mg	erlotinib	25 mg	Film-coated tablet	Oral use
Czech Republic		Sandoz B.V.	Erlotinib Sandoz 100 mg	erlotinib	100 mg	Film-coated tablet	Oral use
Czech Republic		Sandoz B.V.	Erlotinib Sandoz 150 mg	erlotinib	150 mg	Film-coated tablet	Oral use
Czech Republic		Vipharm S.A.	Erlotinib Vipharm 25 mg potahovane tablety	erlotinib	25 mg	Film-coated tablet	Oral use
Czech Republic		Vipharm S.A.	Erlotinib Vipharm 100 mg potahovane tablety	erlotinib	100 mg	Film-coated tablet	Oral use
Czech Republic		Vipharm S.A.	Erlotinib Vipharm 150 mg potahovane tablety	erlotinib	150 mg	Film-coated tablet	Oral use
Denmark		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Denmark		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Denmark		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Denmark	Orifarm Generics A/S		Atovaquone/Proguanil Orifarm	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Denmark	ratiopharm GmBH		Atovaquone/Proguanil ratiopharm	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Horisto	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Horisto	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Denmark	Mylan AB		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
Estonia		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Estonia		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Estonia		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Estonia		Teva B.V.	ERLOTINIB TEVA GENERICS	erlotinib	100 mg	Film-coated tablet	Oral use
Estonia		Teva B.V.	ERLOTINIB TEVA GENERICS	erlotinib	150 mg	Film-coated tablet	Oral use
Finland	ratiopharm GmbH		Atovaquone/Proguanil ratiopharm	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Finland	Sandoz A/S		Rumbabor	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Finland	Sandoz A/S		Rumbabor	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Finland	Mylan AB		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
France		Teva B.V.	Erlotinib Teva Pharma	erlotinib	25 mg	Film-coated tablet	Oral use
France		Teva B.V.	Erlotinib Teva Pharma	erlotinib	100 mg	Film-coated tablet	Oral use
France		Teva B.V.	Erlotinib Teva Pharma	erlotinib	150 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	SAQUINAVIR SANDOZ	saquinavir	500 mg	Film-coated tablet	Oral use
France		Medipha Sante	AMOXICILLINE MEDIPHA 1 g	amoxicillin	1 g	Orodispersible tablet	Oral use
France	Medipha Sante		Amoxicilline Authou	amoxicillin	1 g	Orodispersible tablet	Oral use
France	Sandoz		Atovaquone/Proguanil Sandoz ENFANTS	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
France	Sandoz		Atovaquone/Proguanil Sandoz	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
France	Teva Sante		Atovaquone/Proguanil Teva ENFANTS	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
France	Teva Sante		Atovaquone/Proguanil Teva	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
France	Venipharm		EBACHOI	ebastine	10 mg	Orodispersible tablet	Oral use
France	Venipharm		EBARREN	ebastine	10 mg	Film-coated tablet	Oral use
France	Biogaran		EBASTINE BIOGARAN	ebastine	10 mg	Film-coated tablet	Oral use
France	Biogaran		EBASTINE BIOGARAN	ebastine	10 mg	Orodispersible tablet	Oral use
France	Mylan SAS		EBASTINE MYLAN	ebastine	10 mg	Orodispersible tablet	Oral use
France	Mylan SAS		EBASTINE MYLAN	ebastine	10 mg	Film-coated tablet	Oral use
France	Sanofi Aventis France		EBASTINE ZENTIVA	ebastine	10 mg	Film-coated tablet	Oral use
France	Sanofi Aventis France		EBASTINE ZENTIVA	ebastine	10 mg	Orodispersible tablet	Oral use
France	Venipharm		EBONDE	ebastine	10 mg	Film-coated tablet	Oral use
France	Venipharm		EBONTAN	ebastine	10 mg	Orodispersible tablet	Oral use
France	Venipharm		EBOUDA	ebastine	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
France	Mylan SAS		Eletriptan Mylan	eletriptan	20 mg	Film-coated tablet	Oral use
France	Mylan SAS		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
France	Medipha Sante		Tramadol/Paracétamol Nialex	tramadol/ paracetamol	37.5 mg/ 325mg	Film-coated tablet	Oral use
France	Zydus France		Tramadol/Paracétamol Zydus France	tramadol/ paracetamol	37.5 mg/ 325mg	Film-coated tablet	Oral use
Germany		Pharma Resources GmbH	Etoricoxib PhaRes 30 mg Filmtabletten	etoricoxib	30 mg	Film-coated tablet	Oral use
Germany		Pharma Resources GmbH	Etoricoxib PhaRes 60 mg Filmtabletten	etoricoxib	60 mg	Film-coated tablet	Oral use
Germany		Pharma Resources GmbH	Etoricoxib PhaRes 90 mg Filmtabletten	etoricoxib	90 mg	Film-coated tablet	Oral use
Germany		Pharma Resources GmbH	Etoricoxib PhaRes 120 mg Filmtabletten	etoricoxib	120 mg	Film-coated tablet	Oral use
Germany		Bristol Laboratories Ltd.	Celecoxib axcount 100 mg Hartkapseln	celecoxib	100 mg	Capsule, hard	Oral use
Germany		Bristol Laboratories Ltd.	Celecoxib axcount 200 mg Hartkapseln	celecoxib	200 mg	Capsule, hard	Oral use
Germany		Micro Labs GmbH	Amoxicillin Micro Labs 250 mg	amoxicillin	250 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Amoxicillin Micro Labs 500 mg	amoxicillin	500 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Amoxicillin Micro Labs 750 mg	amoxicillin	750 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany		Micro Labs GmbH	Amoxicillin Micro Labs 1000 mg	amoxicillin	1000 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Rasagilin Micro Labs 1 mg Tabletten	rasagiline	1 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Duloxetin-Hormosan 60 mg magensaftresistente Hartkapseln	duloxetine	60 mg	Capsule, hard	Oral use
Germany		Lupin (Europe) Ltd	Duloxetin-Hormosan 40 mg magensaftresistente Hartkapseln	duloxetine	40 mg	Capsule, hard	Oral use
Germany		Lupin (Europe) Ltd	Duloxetin-Hormosan 30 mg magensaftresistente Hartkapseln	duloxetine	30 mg	Capsule, hard	Oral use
Germany		Lupin (Europe) Ltd	Duloxetin-Hormosan 20 mg magensaftresistente Hartkapseln	duloxetine	20 mg	Capsule, hard	Oral use
Germany		Micro Labs GmbH	Irbesartan / Hydrochlorothiazide Micro Labs 150 mg/12.5 mg Filmtabletten	irbesartan/ hydrochlorothiazide	150 mg/ 12.5mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Irbesartan / Hydrochlorothiazide Micro Labs 300 mg/12.5 mg Filmtabletten	irbesartan/ hydrochlorothiazide	300 mg/ 12.5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany		Micro Labs GmbH	Irbesartan / Hydrochlorothiazide Micro Labs 300 mg /25 mg Filmtabletten	irbesartan/ hydrochlorothiazide	300 mg / 25mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib HEXAL 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib HEXAL 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib HEXAL 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib - 1 A Pharma 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib - 1 A Pharma 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib - 1 A Pharma 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany		Teva B.V.	Erlotinib-ratiopharm 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany	Hexal Aktiengesellschaft		Saquinavir HEXAL 500 mg Filmtabletten	saquinavir	500 mg	Film-coated tablet	Oral use
Germany	ratiopharm GmbH		Atovaquon/Proguanilhydrochlorid-ratiopharm 62,5 mg/25 mg Filmtabletten	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Germany	ratiopharm GmbH		Atovaquon/Proguanilhydrochlorid-ratiopharm 250 mg/100 mg Filmtabletten	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Germany	1A Pharma GmbH		Atovaquon/Proguanilhydrochlorid - 1 A Pharma 250 mg/100 mg Filmtabletten	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Germany	1A Pharma GmbH		Atovaquon/Proguanilhydrochlorid - 1 A Pharma 62,5 mg/25 mg Filmtabletten	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Germany	Hexal Aktiengesellschaft		Malacomp HEXAL	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Germany	Hexal Aktiengesellschaft		Malacomp HEXAL junior	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany	Hormosan Pharma Gesellschaft mit beschränkter Haftung		Pregabalin-Hormosan 25 mg Hartkapseln	pregabalin	25 mg	Capsule, hard	Oral use
Germany	Aristo Pharma GmbH		Eprosartan Aristo 600 mg Filmtabletten	eprosartan	600 mg	Film-coated tablet	Oral use
Germany	Glenmark Arzneimittel GmbH		Celecoxib Glenmark 200 mg Hartkapseln	celecoxib	200 mg	Capsule, hard	Oral use
Germany	Glenmark Arzneimittel GmbH		Celecoxib Glenmark 100 mg Hartkapseln	celecoxib	100 mg	Capsule, hard	Oral use
Greece		Genepharm SA	ERLOTINIB/GENEPHARM	erlotinib	25 mg	Film-coated tablet	Oral use
Greece		Genepharm SA	ERLOTINIB/GENEPHARM	erlotinib	100 mg	Film-coated tablet	Oral use
Greece		Genepharm SA	ERLOTINIB/GENEPHARM	erlotinib	150 mg	Film-coated tablet	Oral use
Hungary		Vipharm S.A.	ERLOTINIB VIPHARM 100 mg filmtabletta	erlotinib	100 mg	Film-coated tablet	Oral use
Hungary		Vipharm S.A.	ERLOTINIB VIPHARM 150 mg filmtabletta	erlotinib	150 mg	Film-coated tablet	Oral use
Hungary		Vipharm S.A.	ERLOTINIB VIPHARM 25 mg filmtabletta	erlotinib	25 mg	Film-coated tablet	Oral use
Hungary		Sandoz B.V.	ERLOTINIB Sandoz 25 mg filmtabletta	erlotinib	25 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Hungary		Sandoz B.V.	ERLOTINIB Sandoz 100 mg filmtabletta	erlotinib	100 mg	Film-coated tablet	Oral use
Hungary		Sandoz B.V.	ERLOTINIB Sandoz 150 mg filmtabletta	erlotinib	150 mg	Film-coated tablet	Oral use
Hungary		Lupin (Europe) Ltd	Pregabalin Merck 25 mg kemény kapszula	pregabalin	25 mg	Capsule, hard	Oral use
Iceland	Lyfis ehf.		Celecoxib LYFIS	celecoxib	100 mg	Capsule, hard	Oral use
Iceland	Lyfis ehf.		Celecoxib LYFIS	celecoxib	200 mg	Capsule, hard	Oral use
Ireland		Sandoz B.V.	Erlotinib Rowex	erlotinib	25 mg	Film-coated tablet	Oral use
Ireland		Sandoz B.V.	Erlotinib Rowex	erlotinib	100 mg	Film-coated tablet	Oral use
Ireland		Sandoz B.V.	Erlotinib Rowex	erlotinib	150 mg	Film-coated tablet	Oral use
Italy		Teva B.V.	ERLOTINIB TEVA	erlotinib	25 mg	Film-coated tablet	Oral use
Italy		Teva B.V.	ERLOTINIB TEVA	erlotinib	100 mg	Film-coated tablet	Oral use
Italy		Teva B.V.	ERLOTINIB TEVA	erlotinib	150 mg	Film-coated tablet	Oral use
Italy		Sandoz B.V.	ERLOTINIB SANDOZ	erlotinib	100 mg	Film-coated tablet	Oral use
Italy		Sandoz B.V.	ERLOTINIB SANDOZ	erlotinib	150 mg	Film-coated tablet	Oral use
Italy	Sandoz S.p.A.		ATOVAQUONE E PROGUANILE SANDOZ	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Italy	Sandoz S.p.A.		ATOVAQUONE E PROGUANILE SANDOZ	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Italy	Sandoz S.p.A.		SAQUINAVIR SANDOZ	saquinavir	500 mg	Film-coated tablet	Oral use
Italy	Mylan S.p.A.		ELETRIPTAN MYLAN	eletriptan	20 mg	Film-coated tablet	Oral use
Italy	Mylan S.p.A.		ELETRIPTAN MYLAN	eletriptan	40 mg	Film-coated tablet	Oral use
Latvia		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 25 mg film-coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Latvia		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 100 mg film-coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Latvia		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 150 mg film-coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Latvia		Sandoz B.V.	Erlotinib Sandoz 25 mg film-coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Latvia		Sandoz B.V.	Erlotinib Sandoz 100 mg film-coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Latvia		Sandoz B.V.	Erlotinib Sandoz 150 mg film-coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Latvia		Accord Healthcare Ltd	Saquinavir Accord 500 mg film-coated tablets	saquinavir	500 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Lithuania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss	erlotinib	25 mg	Film-coated tablet	Oral use
Lithuania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss	erlotinib	100 mg	Film-coated tablet	Oral use
Lithuania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss	erlotinib	150 mg	Film-coated tablet	Oral use
Lithuania		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Lithuania		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Lithuania		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Lithuania		Teva B.V.	Erlotinib Teva Generics	erlotinib	150 mg	Film-coated tablet	Oral use
Lithuania		Accord Healthcare Ltd	Saquinavir Accord 500 mg plėvele dengtos tabletės	saquinavir	500 mg	Film-coated tablet	Oral use
Luxembourg		Sandoz S.A.	Saquinavir	saquinavir	500 mg	Film-coated tablet	Oral use
Luxembourg		Micro Labs GmbH	Irbesartan / Hydrochlorothiazide Micro Labs 150 mg/12.5 mg Filmtabletten	irbesartan/ hydrochlorothiazide	150 mg/ 12.5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Luxembourg		Micro Labs GmbH	Irbesartan / Hydrochlorothiazide Micro Labs 300 mg/12.5 mg Filmtabletten	irbesartan/ hydrochlorothiazide	300 mg/ 12.5 mg	Film-coated tablet	Oral use
Luxembourg		Micro Labs GmbH	Irbesartan / Hydrochlorothiazide Micro Labs 300 mg /25 mg Filmtabletten	irbesartan/ hydrochlorothiazide	300 mg / 25mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib-ratiopharm 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib-ratiopharm 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib-ratiopharm 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib Ratiopharm	erlotinib	25 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib Ratiopharm	erlotinib	100 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib Ratiopharm	erlotinib	150 mg	Film-coated tablet	Oral use
Luxembourg		Micro Labs GmbH	Rasagilin Micro Labs 1 mg Tabletten	rasagiline	1 mg	Film-coated tablet	Oral use
Luxembourg	Sandoz S.A.		Malaprotec	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Luxembourg	Sandoz S.A.		Malaprotec	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Luxembourg	ratiopharm GmbH		Atovaquon/Proguanilhydrochlorid-ratiopharm 62,5 mg/25 mg Filmtabletten	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Luxembourg	ratiopharm GmbH		Atovaquon/Proguanilhydrochlorid-ratiopharm 250 mg/100 mg Filmtabletten	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Malta	1A Pharma GmbH		Reprapog	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Malta	1A Pharma GmbH		Reprapog	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Norway	Mylan AB		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Eletriptan Mylan	eletriptan	20 mg	Film-coated tablet	Oral use
Norway	Orifarm Generics A/S		Atovaquone/Proguanil Orifarm	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Poland		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Poland		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Poland		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Poland		Vipharm S.A.	Erlotinib Vipharm	erlotinib	25 mg	Film-coated tablet	Oral use
Poland		Vipharm S.A.	Erlotinib Vipharm	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Poland		Vipharm S.A.	Erlotinib Vipharm	erlotinib	150 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH		Saquinavir Sandoz	saquinavir	500 mg	Film-coated tablet	Oral use
Portugal		Brown & Burk UK, Ltd.	Amoxicilina Brown	amoxicillin	250 mg	Film-coated tablet	Oral use
Portugal		Brown & Burk UK, Ltd.	Amoxicilina Brown	amoxicillin	500 mg	Film-coated tablet	Oral use
Portugal		Brown & Burk UK, Ltd.	Amoxicilina Brown	amoxicillin	750 mg	Film-coated tablet	Oral use
Portugal		Brown & Burk UK, Ltd.	Amoxicilina Brown	amoxicillin	1000 mg	Film-coated tablet	Oral use
Portugal		Teva Pharma - Produtos Farmacêuticos, Lda.	Erlotinib Zidrium	erlotinib	25 mg	Film-coated tablet	Oral use
Portugal		Teva Pharma - Produtos Farmacêuticos, Lda.	Erlotinib Zidrium	erlotinib	100 mg	Film-coated tablet	Oral use
Portugal		Teva Pharma - Produtos Farmacêuticos, Lda.	Erlotinib Zidrium	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Portugal		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Portugal		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Portugal		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Portugal		Hetero Europe, S.L.	Celecoxib Hetero	Celecoxib	100 mg	Capsule, hard	Oral use
Portugal		Hetero Europe, S.L.	Celecoxib Hetero	Celecoxib	200 mg	Capsule, hard	Oral use
Portugal		Lupin (Europe) Ltd	Pregabalina Merck	Pregabalin	25 mg	Capsule, hard	Oral use
Portugal	Hetero Europe, S.L.		Eprosartan Hetero	eprosartan	600 mg	Film-coated tablet	Oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A.		Saquinavir Farmoz	saquinavir	500 mg	Film-coated tablet	Oral use
Portugal	Lupin (Europe) Ltd		Pregabalina Lupin	pregabalin	25 mg	Capsule, hard	Oral use
Romania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 25 mg film-coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Romania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 100 mg film-coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Romania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 150 mg film-coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Romania		Teva B.V.	Erlotinib Teva Pharma 25 mg, film coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Romania		Teva B.V.	Erlotinib Teva Pharma 100 mg, film coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Romania		Teva B.V.	Erlotinib Teva Pharma 150 mg, film coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Romania		Sandoz B.V.	Erlotinib Sandoz 25 mg, film coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Romania		Sandoz B.V.	Erlotinib Sandoz 100 mg, film coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Romania		Sandoz B.V.	Erlotinib Sandoz 150 mg, film coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia		Sandoz B.V.	Erlotinib Sandoz 100 mg, 150 mg	erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia		Sandoz B.V.	Erlotinib Sandoz 100 mg, 150 mg	erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia		Vipharm S.A.	Erlotinib Vipharm 25 mg, 100 mg, 150 mg	erlotinib	25 mg	Film-coated tablet	Oral use
Slovakia		Vipharm S.A.	Erlotinib Vipharm 25 mg, 100 mg, 150 mg	erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia		Vipharm S.A.	Erlotinib Vipharm 25 mg, 100 mg, 150 mg	erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia		PharmaSwiss Česká republika s.r.o.	ERLOTIB 25 mg, 100 mg, 150 mg	erlotinib	25 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Slovakia		PharmaSwiss Česká republika s.r.o.	ERLOTIB 25 mg, 100 mg, 150 mg	erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia		PharmaSwiss Česká republika s.r.o.	ERLOTIB 25 mg, 100 mg, 150 mg	erlotinib	150 mg	Film-coated tablet	Oral use
Slovenia		Sandoz B.V.	Erlotinib Sandoz 25 mg flmsko obložene tablete	erlotinib	25 mg	Film-coated tablet	Oral use
Slovenia		Sandoz B.V.	Erlotinib Sandoz 100 mg filmsko obložene tablete	erlotinib	100 mg	Film-coated tablet	Oral use
Slovenia		Sandoz B.V.	Erlotinib Sandoz 150 mg filmsko obložene tablete	erlotinib	150 mg	Film-coated tablet	Oral use
Spain		Sandoz B.V.	Erlotinib Sandoz 25 mg, 100 mg and 150 mg comprimidos recubiertos con película EFG	erlotinib	25 mg	Film-coated tablet	Oral use
Spain		Sandoz B.V.	Erlotinib Sandoz 25 mg, 100 mg and 150 mg comprimidos recubiertos con película EFG	erlotinib	100 mg	Film-coated tablet	Oral use
Spain		Sandoz B.V.	Erlotinib Sandoz 25 mg, 100 mg and 150 mg comprimidos recubiertos con película EFG	erlotinib	150 mg	Film-coated tablet	Oral use
Spain		Brill Pharma, S.L.	Celecoxib Brill Pharma 100 mg and 200 mg cápsulas duras	celecoxib	100 mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Spain		Brill Pharma, S.L.	Celecoxib Brill Pharma 100 mg and 200 mg cápsulas duras	celecoxib	200 mg	Capsule, hard	Oral use
Spain		Accord Healthcare Ltd	Saquinavir Accord 500 mg comprimidos recubiertos con película EFG	saquinavir	500 mg	Film-coated tablet	Oral use
Spain	Teva Pharma, S.L.U.		Atovacuona/Hidrocloruro de Proguanil Teva 250 mg/100 mg comprimidos recubiertos con película EFG	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Atovacuona/Hidrocloruro de Proguanil Sandoz 250 mg/100 mg comprimidos recubiertos con película EFG	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Spain	Pensa Pharma, S.A.U.		Eprosartan Pensa 600 mg comprimidos recubiertos con película EFG	eprosartan	600 mg	Film-coated tablet	Oral use
Spain	Industria Química Y Farmacéutica VIR, S.A.		Celecoxib VIR 200 mg cápsulas duras EFG	celecoxib	200 mg	Capsule, hard	Oral use
Sweden		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Sweden		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Sweden		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Horisto	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Horisto	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Sweden	Mylan AB		Eletriptan Mylan	eletriptan	20 mg	Film-coated tablet	Oral use
Sweden	Mylan AB		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
Sweden	Orifarm Generics A/S		Atovaquone/Proguanil Orifarm	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
Sweden	Medical Valley Invest AB		Celecoxib Medical Valley	celecoxib	100 mg	Capsule, hard	Oral use
Sweden	Medical Valley Invest AB		Celecoxib Medical Valley	celecoxib	200 mg	Capsule, hard	Oral use
The Netherlands		PharmaSwiss Česká republika s.r.o.	ERLOTIB	erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands		PharmaSwiss Česká republika s.r.o.	ERLOTIB	erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands		PharmaSwiss Česká republika s.r.o.	ERLOTIB	erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands		Accord Healthcare Ltd	Saquinavir Accord	saquinavir	500 mg	Film-coated tablet	Oral use
The Netherlands		Teva B.V.	Erlotinib PCH	erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands		Teva B.V.	Erlotinib PCH	erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands		Teva B.V.	Erlotinib PCH	erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands	Teva Nederland B.V.		Atovaquon/Proguanil HCl Teva	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
The Netherlands	Teva Nederland B.V.		Atovaquon/Proguanil HCl Teva	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Atovaquon/Proguanil HCl Sandoz	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Atovaquon/Proguanil HCl Sandoz	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
The Netherlands	Sandoz B.V.		Atovaquon/Proguanil HCl Sandoz	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Atovaquon/Proguanil HCl Sandoz	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Saquinavir Sandoz	saquinavir	500 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Saquinavir Sandoz	saquinavir	500 mg	Film-coated tablet	Oral use
The Netherlands	Hetero Europe, S.L.		Celecoxib Hetero	celecoxib	100 mg	Capsule, hard	Oral use
The Netherlands	Hetero Europe, S.L.		Celecoxib Hetero	celecoxib	200 mg	Capsule, hard	Oral use
United Kingdom		Brown & Burk UK, Ltd.	ROSUVASTATIN 5 MG FILM-COATED TABLETS	rosuvastatin	5 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	ROSUVASTATIN 10MG FILM-COATED TABLETS	rosuvastatin	10 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	ROSUVASTATIN 20 MG FILM-COATED TABLETS	rosuvastatin	20 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	ROSUVASTATIN 40 MG FILM-COATED TABLETS	rosuvastatin	40 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	TRAMADOL / PARACETAMOL BROWN & BURK 37.5 MG / 325 MG FILM-COATED TABLETS	tramadol/ paracetamol	37.5 mg/ 325 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
United Kingdom		Brown & Burk UK, Ltd.	Irbesartan/Hydrochlorothiazide Brown & Burk 150mg/12.5mg Film-coated tablets	irbesartan/ hydrochlorothiazide	150 mg/ 12.5 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	Irbesartan/Hydrochlorothiazide Brown & Burk 300mg/12.5mg Film-coated tablets	irbesartan/ hydrochlorothiazide	300 mg/ 12.5 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	Irbesartan/Hydrochlorothiazide Brown & Burk 300mg/25mg Film-coated tablets	irbesartan/ hydrochlorothiazide	300 mg / 25mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	Rasagiline Brown & Burk 1mg Tablets	rasagiline	1 mg	Film-coated tablet	Oral use
United Kingdom		Lupin (Europe) Ltd	Duloxetine Lupin 20mg GR capsules	duloxetine	20 mg	Capsule	Oral use
United Kingdom		Lupin (Europe) Ltd	Duloxetine Lupin 30mg GR capsules	duloxetine	30 mg	Capsule	Oral use
United Kingdom		Lupin (Europe) Ltd	Duloxetine Lupin 40mg GR capsules	duloxetine	40 mg	Capsule	Oral use
United Kingdom		Lupin (Europe) Ltd	Duloxetine Lupin 60mg GR capsules	duloxetine	60 mg	Capsule	Oral use
United Kingdom	Teva UK Limited		MAFAMOZ 250MG/100MG FILM-COATED TABLETS	atovaquone/ proguanil	250 mg/ 100mg	Tablet	Oral use
United Kingdom	Teva UK Limited		MAFAMOZ 62.5MG/25 MG FILM-COATED TABLETS	atovaquone/ proguanil	62.5 mg/ 25mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
United Kingdom	Sandoz Limited		REPRAPOG 62.5 MG/25 MG FILM-COATED TABLETS	atovaquone/ proguanil	62.5 mg/ 25mg	Film-coated tablet	Oral use
United Kingdom	Sandoz Limited		REPRAPOG 250 MG/100 MG FILM-COATED TABLETS	atovaquone/ proguanil	250 mg/ 100mg	Film-coated tablet	Oral use
United Kingdom	Brown & Burk UK Limited		AMOXICILLIN SUGAR FREE 3G POWDER FOR ORAL SUSPENSION SACHETS	amoxicillin	3443.35 mg	Powder for oral suspension	Oral use
United Kingdom	Hetero Europe, S.L.		EPROSARTAN 300 MG FILM-COATED TABLETS	eprosartan	300 mg	Film-coated tablet	Oral use
United Kingdom	Hetero Europe, S.L.		EPROSARTAN 400 MG FILM-COATED TABLETS	eprosartan	400 mg	Film-coated tablet	Oral use
United Kingdom	Hetero Europe, S.L.		EPROSARTAN 600 MG FILM-COATED TABLETS	eprosartan	600 mg	Film-coated tablet	Oral use
United Kingdom	Bristol Laboratories Limited		CELECOXIB CAPSULES, HARD 100MG	celecoxib	100 mg	Capsule, hard	Oral use
United Kingdom	Bristol Laboratories Limited		CELECOXIB CAPSULES, HARD 200MG	celecoxib	200 mg	Capsule, hard	Oral use
United Kingdom	Lupin (Europe) Ltd		Pregabalin Lupin 25mg hard capsules	pregabalin	25 mg	Capsule, hard	Oral use

22 July 2016
EMA/499815/2016
Procedure Management and Business Support

Marketing authorisations which are recommended for maintenance and marketing authorisation applications for which bioequivalence vis-à-vis the EU reference medicinal product has been established as adopted by the CHMP on 21 July 2016

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1443

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Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Austria		Lupin (Europe) Ltd	Abacavir/Lamivudin Aristo 600 mg/300 mg Filmtabletten	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Austria		Lupin (Europe) Ltd	Abacavir/Lamivudin Sandoz 600 mg/300 mg - Filmtabletten	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Belgium		Lupin (Europe) Ltd	Abacavir/Lamivudin Sandoz	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Belgium		Mylan bvba	Abacavir/Lamivudin Mylan	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Bulgaria	Sandoz d.d.		Abacavir/Lamivudin Sandoz	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Croatia		Lupin (Europe) Ltd	Abakavir/Lamivudin Sandoz 600 mg/300 mg filmom obložene tablete	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Cyprus		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Denmark		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Denmark		Mylan AB	Abacavir /Lamivudine Mylan	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Estonia		Lupin (Europe) Ltd	ABACAVIR/LAMIVUDINE SANDOZ	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Finland		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Finland		Mylan AB	Abacavir/Lamivudine Mylan	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
France		Venipharm	BAMIVENI	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
France		Venipharm	BAMIVUDINE	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
France		Venipharm	VIRAMUDINE	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudin 600 mg / 300 mg Filmtabletten	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudine Hormosan 600 mg/300 mg Filmtabletten	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudin HEXAL 600 mg/300 mg Filmtabletten	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudin Aristo 600 mg/300 mg Filmtabletten	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudin Klinge 600 mg/300 mg Filmtabletten	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Ireland		Generics (UK) Limited	Abacavir / Lamivudine	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Ireland		Lupin (Europe) Ltd	Abacavir/Lamivudine Rowex	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Italy		Lupin (Europe) Ltd	ABACAVIR E LAMIVUDINA LUPIN	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Italy		Lupin (Europe) Ltd	ABACAVIR E LAMIVUDINA SANDOZ	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Italy		Lupin (Europe) Ltd	ABACAVIR E LAMIVUDINA MYLAN	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Italy		Lupin (Europe) Ltd	ABACAVIR E LAMIVUDINA ARISTO	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Lithuania		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz 600mg/300 mg plėvele dengtos tabletės	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Norway		Mylan AB	Abacavir/Lamivudin Mylan	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Poland		Lupin (Europe) Ltd	Abacavir+Lamivudine Sandoz	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Poland		Lupin (Europe) Ltd	Abacavir + Lamivudine Mylan	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Portugal		Lupin (Europe) Ltd	Abacavir + Lamivudina Lupin	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Portugal		Lupin (Europe) Ltd	Abacavir + Lamivudina Sandoz	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Portugal		Mylan, Lda.	Abacavir + Lamivudina Mylan	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Romania		Lupin (Europe) Ltd	Abacavir/lamivudină Sandoz 600 mg/300 mg, film-coated tablets	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use

Member State EU / EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Slovenia		Lupin (Europe) Ltd	Abakavir/lamivudin Sandoz 600 mg/300 mg filmsko obložene tablete	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Spain		Lupin (Europe) Ltd	Abacavir/Lamivudina Amneal 600 mg/300 mg comprimidos recubiertos con película EFG	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Spain		Lupin (Europe) Ltd	Abacavir/Lamivudina Aristo 600 mg/300 mg comprimidos recubiertos con película EFG	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Spain		Sandoz B.V.	Abacavir/Lamivudina Sandoz 600 mg/300 mg comprimimidos recubiertos con película EFG	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		Abacavir/Lamivudina Mylan 600 mg/300 mg comprimidos recubiertos con película EFG	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Sweden		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Sweden		Mylan AB	Abacavir /Lamivudine Mylan	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
The Netherlands		Lupin (Europe) Ltd	Abacavir/Lamivudine Aristo	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
The Netherlands		Lupin (Europe) Ltd	Abacavir/Lamivudine Lupin	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
The Netherlands		Lupin (Europe) Ltd	Abacavir/Lamivudine Lupin	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
United Kingdom		Aristo Pharma GmbH	Abacavir/lamivudine 600mg/300mg film coated tablets	abacavir/ lamivudine	600 mg/ 300 mg	Tablet	Oral use
United Kingdom		Lupin (Europe) Ltd	Abacavir/lamivudine 600mg/300mg film coated tablets	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
United Kingdom		Lupin (Europe) Ltd	Abacavir/lamivudine 600mg/300mg film coated tablets	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
United Kingdom		Generics (UK) Limited	Abacavir/lamivudine 600mg/300mg film coated tablets	abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use