



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders and applicants in the member states for medicinal products which have been authorised or are pending approval based on clinical trials performed at Panexcell Clinical Laboratories Priv. Ltd

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1494

Please note that this draft Annex I will be updated to amend information on concerned products/ MAHs/Applicants

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Denmark		Laurus Generics GmbH	Atazanavir Laurus	Atazanavir	150 mg	Capsule, hard	Oral use
Denmark		Laurus Generics GmbH	Atazanavir Laurus	Atazanavir	200 mg	Capsule, hard	Oral use
Denmark		Laurus Generics GmbH	Atazanavir Laurus	Atazanavir	300 mg	Capsule, hard	Oral use
Finland		Laurus Generics GmbH	Atazanavir Laurus	Atazanavirsulfat	150 mg	Capsule, hard	Oral use
Finland		Laurus Generics GmbH	Atazanavir Laurus	Atazanavirsulfat	200 mg	Capsule, hard	Oral use
Finland		Laurus Generics GmbH	Atazanavir Laurus	Atazanavirsulfat	300 mg	Capsule, hard	Oral use
France	ALMUS FRANCE		Amoxicilline Almus Pharma 500 mg gélule	AMOXICILLIN TRIHYDRATE	500 mg	Capsule, hard	Oral use
France	Baxter Holding B.V.		FER BAXTER 20 mg/mL, solution pour injection/perfusion	IRON SUCROSE	20 mg/mL	solution for injection/infusion	Intravenous use
Germany		Laurus Generics GmbH	Atazanavir Laurus 150 mg Hartkapseln	Atazanavir sulphate	150 mg	Capsule, hard	Oral use
Germany		Laurus Generics GmbH	Atazanavir Laurus 200 mg Hartkapseln	Atazanavir sulphate	200 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Laurus Generics GmbH	Atazanavir Laurus 300 mg Hartkapseln	Atazanavir sulphate	300 mg	Capsule, hard	Oral use
Germany	Baxter Holding B.V.		Eisen Sucrose Baxter 20 mg/ml Injektions-/Infusionslösung	iron sucrose	20 mg/ml	solution for injection/infusion	Intravenous use
Malta	NEXCAPE PHARMACEUTICALS LIMITED		AMOXICILLIN 250MG CAPSULES	AMOXICILLIN TRIHYDRATE	250mg	Capsule, hard	Oral use
Malta	NEXCAPE PHARMACEUTICALS LIMITED		AMOXICILLIN 500MG CAPSULES	AMOXICILLIN TRIHYDRATE	500mg	Capsule, hard	Oral use
The Netherlands		Laurus Generics GmbH	Atazanavir Laurus 150 mg, hard capsules	atazanavir	150 mg	Capsule, hard	Oral use
The Netherlands		Laurus Generics GmbH	Atazanavir Laurus 200 mg, hard capsules	atazanavir	200 mg	Capsule, hard	Oral use
The Netherlands		Laurus Generics GmbH	Atazanavir Laurus 300 mg, hard capsules	atazanavir	300 mg	Capsule, hard	Oral use
Spain	ALMUS FARMACEUTICA, S.A.		AMOXICILINA ALMUS 500 mg cápsulas duras EFG	AMOXICILLIN	500 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Sweden		Laurus Generics GmbH	Atazanavir Laurus	Atazanavir sulfate	150 mg	Capsule, hard	Oral use
Sweden		Laurus Generics GmbH	Atazanavir Laurus	Atazanavir sulfate	200 mg	Capsule, hard	Oral use
Sweden		Laurus Generics GmbH	Atazanavir Laurus	Atazanavir sulfate	300 mg	Capsule, hard	Oral use
United Kingdom	MANX HEALTHCARE LIMITED		AZITHROMYCIN 250MG CAPSULES	AZITHROMYCIN DIHYDRATE	250mg	Capsule, hard	Oral use
United Kingdom	MANX HEALTHCARE LIMITED		CARBOCISTEINE 375MG CAPSULE HARD	CARBOCISTEINE	375mg	Capsule, hard	Oral use
United Kingdom		STRANDHAVEN LIMITED	CARBOCISTEINE 375 MG CAPSULES, HARD	CARBOCISTEINE	375MG	Capsule, hard	Oral use
United Kingdom		DAWA LIMITED	AMOXICILLIN 250 MG CAPSULES	AMOXICILLIN TRIHYDRATE	250MG	Capsule, hard	Oral use
United Kingdom		DAWA LIMITED	AMOXICILLIN 500 MG CAPSULE	AMOXICILLIN TRIHYDRATE	500MG	Capsule, hard	Oral use
United Kingdom		SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	TRIMETHOPRIM 100MG TABLETS	TRIMETHOPRIM	100MG	tablet	Oral use
United Kingdom		SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	TRIMETHOPRIM 200MG TABLETS	TRIMETHOPRIM	200MG	tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	BAXTER HEALTHCARE LIMITED		IRON SUCROSE 20 MG IRON/ML, SOLUTION FOR INJECTION /INFUSION	IRON SUCROSE	20MG/ML	CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	Intravenous use
United Kingdom		LAURUS GENERICS GMBH	ATAZANAVIR LAURUS 150 MG CAPSULES, HARD	ATAZANAVIR SULFATE	150MG	Capsule, hard	Oral use
United Kingdom		LAURUS GENERICS GMBH	ATAZANAVIR LAURUS 200 MG, CAPSULES, HARD	ATAZANAVIR SULFATE	200MG	Capsule, hard	Oral use
United Kingdom		LAURUS GENERICS GMBH	ATAZANAVIR LAURUS 300 MG, CAPSULES, HARD	ATAZANAVIR SULFATE	300MG	Capsule, hard	Oral use
United Kingdom	NEXCAPE PHARMACEUTICALS LIMITED		AMOXICILLIN 250MG CAPSULES	AMOXICILLIN TRIHYDRATE	250mg	Capsule, hard	Oral use
United Kingdom	NEXCAPE PHARMACEUTICALS LIMITED		AMOXICILLIN 500MG CAPSULES	AMOXICILLIN TRIHYDRATE	500mg	Capsule, hard	Oral use