

FDF-CTD DOSSIER

INN	Dosage Form	Therapeutic Class	Available Dossier	Reference Product
Acitretin	Capsule 7.5-10-12.5-25 mg	Antipsoriatic	EU-RoW	Soriatane
Abiraterone New	Film-Coated Tablet 250-500 mg	Antineoplastic	US-EU-RoW	Zytiga
Clofarabine	Vial-Liquid 20 mg	Antineoplastic	EU-RoW	Clolar/Evoltra
Daptomycin	Vial-Lyo 350-500 mg	Antibacterial	US-EU-RoW	Cubicin
Deferoxamine mesylate	Vial-Lyo 500-2,000 mg	Iron chelating agent	US-EU-RoW	Desferal
Lenvatinib mesylate New	Capsule 4-10 mg	Antineoplastic	US-EU-RoW	Lenvima
Methylergonovine New	Film-Coated Tablet 0.2 mg	PPH, anti haemorrhage	US-EU-RoW	Methergine
Nintedanib esylate New	Soft-Gel 100-150 mg	Antineoplastic, IPF	US-EU-RoW	Ofev
Olaparib New	Film-Coated Tablet 100-150 mg	Antineoplastic	US-EU-RoW	Lymparza
Teriflunomide	Film-Coated Tablet 7-14 mg	Agents for multiple	EU-RoW	Aubagio
Valgancyclovir	Film-Coated Tablet 450 mg	Antiviral	EU-RoW	Valcyte

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