



**POLFA TARCHOMIN S.A.**

Pharmaceutical Manufacturing

**Out-licencing Portfolio**



## Dermatology

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Dermatology	Neomycin sulphate (OTC)	Cutaneous spray, suspension	11,72 mg/g	WEU	Available
Dermatology	Neomycin sulphate (RX)	Cutaneous spray, suspension	11,72 mg/g	WEU	Available
Dermatology	Hydrocortisone (OTC)	Cutaneous spray, suspension	1,372 mg/g	WEU	Available
Dermatology	Miconazole (OTC)	Gel	20 mg/g	WEU	Available



## CNS

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
CNS	Lorazepam (RX)	Tablets	0,5 mg; 1 mg; 2,5 mg	Tavor (Wyeth)	Available
CNS	Lorazepam (RX)	Solution for injection	2 mg/ml; 4 mg/ml	Temesta (Pfizer)	Available
CNS	Clonazepam (RX)	Tablets	0,5 mg; 2,0 mg	Rivotril (Roche)	Available
CNS	Clonazepam (RX)	Solution for injection	1 mg/ml	Rivotril (Roche)	Available



# Anti-infectives

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Anti-infectives	Cloxacillin sodium (RX)	Powder for solution for injection/infusion	1g; 2g	WEU	Available
Anti-infectives	Doxycycline (Rx)	Solution for infusion	20mg/ml	VIBRAMYCIN /WEU	Q4 2023
Anti-infectives	Colistimethate sodium (RX)	Powder (lyophilisate) for solution for injection and infusion	1 000 000 IU	Colomycin (Forest Laboratories)	Available
Anti-infectives	Colistimethate sodium	Powder for injection / infusion solution or nebuliser solution	1 000 000 IU; 2 000 000 IU; 3 000 000 IU	Colomycin (Forest Laboratories) (RX)	Available
Anti-infectives / Antifungals	Nystatin (RX)	Granulate/powder for suspension	100 000 IU/ml	WEU	Available
Anti-infectives	Ampicillin sodium (RX)	Powder for solution for injection	1g; 2g	Doktacillin (Meda)	Available
* Anti-infectives	Ampicillin	Powder for solution for injection	500 mg; 1 g; 2 g	WEU (RX)	Available
* Anti-infectives	Benzylpenicillin potassium	Powder for solution for injection/infusion	3 000 000 IU	WEU (RX)	Available
Anti-infectives	Benzylpenicillin potassium	Powder for solution for injection/infusion	5 000 000 IU	Benzylpenicillin (Meda)	Available
Anti-infectives	Fosfomicin trometamol (RX)	Granulate powder for suspension	3g	Monural (Zambon)	Q2 2024
Anti-infectives	Fosfomicin sodium (RX)	Powder for solution for infusion	40mg/ml	InfectoFos	Q2 2025



## Anti-infectives

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Anti-infectives	Lymecycline (RX)	Hard capsules	150mg, 300mg	Tetralysal (Galderma)	Q3 2025
Anti-infectives	Amoxicillin+ Clavulanic acid	Powder for oral suspension	(600mg+ 42,9 mg)/5ml	Augmentin ES (GSK) (RX)	Q3 2024
Anti-infectives	Ampicilin+ Sulbactam	Powder for solution for injection/ infusion	500mg+250mg 1g+500mg 2g+1g	Unasyn (Pfizer) (RX)	Q1 2024
* Anti-infectives	Rifampicinum	Hard capsules	150 mg; 300 mg	Rifadin (Sanofi-Aventis Ireland Limited T/A SANOFI)	Q4 2026
* Anti-infectives	Rifampicinum + Isoniazidum	Hard capsules	150 mg + 100mg	Rifinah (Sanofi-Aventis Ireland Limited T/A SANOFI)	Q4 2026
* Anti-infectives	Phenoxymethylpenicillinum Potassium	Coated tablets	800 mg, 1000 mg	Kåvepenin (MEDA AG)	Q3 2025
* Anti-infectives	Phenoxymethylpenicillinum Potassium	Granulate for oral suspension	100 mg/ml	Kåvepenin (MEDA AG)	Q3 2025



## Diabetology

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Diabetology	Sitagliptin phosphate	Coated tablets	25 mg; 50 mg; 100 mg	Januvia (MSD) (RX)	Q4 2024
Diabetology	Metformin hydrochloride	XR tablets	1000 mg	Glucophage XR (Merck) (RX)	Q1 2025
Diabetology	Metformin hydrochloride	XR tablets	500 mg; 750 mg	Glucophage XR (Merck) (RX)	Q1 2026
* Diabetology	Empagliflozin	Coated tablets	10 mg; 25 mg	Jardiance (Boehringer Ingelheim International GmbH)	Q2 2027
* Diabetology	Dapagliflozin	Coated tablets	5 mg; 10 mg	Forxiga (Bristol-Myers Squibb/AstraZeneca EEIG)	Q3 2025

## Antifungals

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Antifungals	Nystatin	Powder for oral suspension	100 000 IU/ml	WEU (RX)	Available
Antifungals	Caspofungin acetate	Powder for infusion solution	50 mg; 70 mg	Cancidas (Merck & Sharp & Dohme) (RX)	Q2 2024
Antifungals	Micafungin sodium salt	Powder for infusion solution	50 mg; 100 mg	Mycamine (Astellas) (RX)	Q3 2024



## Pain Management

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Pain management (neurology)	B1 –Thiamine hydrochloride & B6 – pyridoxine hydrochloride & B12 – cyanocobalamin (RX)	Coated tablets	100 mg + 200 mg + 0,2 mg	Neuromultivit (GL Pharma)	Q2 2024
Pain management	Metamizole Sodium	Solution for injection	1 g / 2 ml (0,5 g/ml); 2,5 g / 5 ml (0,5 g/ml)	Novalgine (Sanofi Aventis Deutschland GmbH)	Q3 2024
Pain management	Morphine	Solution for infusion	10mg/ml 20mg/ml	Morfin Epidural Meda	Q3 2024



## Oncology

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Oncology	Azacitadine (RX)	Powder for solution for injection	100 mg	Vidaza (Celgene)	Available
Oncology	Bortezomib (RX)	Powder for solution for injection	3,5 mg	Velcade (Janssen-Cilag)	Available
Oncology	Fulvestrant	Solution for injection (pre-filled syringes)	250 mg/ 5 ml	Faslodex (Astra Zeneca ) (RX)	Q1 2027

## Rheumatology

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Rheumatology	Methotrexate (RX)	Solution for injection (pre-filled syringes)	50mg/ml	Metex (Medac)	Q3 2026
Rheumatology	Hydroxy- chloroquine	Coated tablets	200mg	Plaquenil (Sanofi)	Available



# Anesthesiology

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Anesthesiology	Sugammadex	Solution for injection	100 mg/ml	Bridion (MSD) (RX)	Q3 2025

# Nephrology

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Nephrology (kidney stones)	Potassium citrate monohydrate (RX)	Tablets	1080 mg	WEU	Available



## Cardiology

Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Cardiology	Noradrenaline	Concentrate for solution for infusion	1 mg / 1 ml (1mg/ml); 4 mg / 4 ml (1 mg/ml)	WEU (RX)	Q4 2024

## Various

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Therapy area	Molecule	Form	Strenght/ Dosage	RLD/WEU	Dossier availability date
Various	Potassium iodide	Tablets	65 mg	Potassium iodide (Hemo Medika / Potassium iodide G.L. Pharma)	Available



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**API Portfolio**



## API Portfolio

API	CAS No
Erythromycin Cyclic 11,12-Carbonate	55224-05-0
Erythromycin base	114-07-8
Ifosfamide	3778-73-2
Pamidronate disodium pentahydrate	109552-15-0
Zoledronic Acid monohydrate	165800-06-6