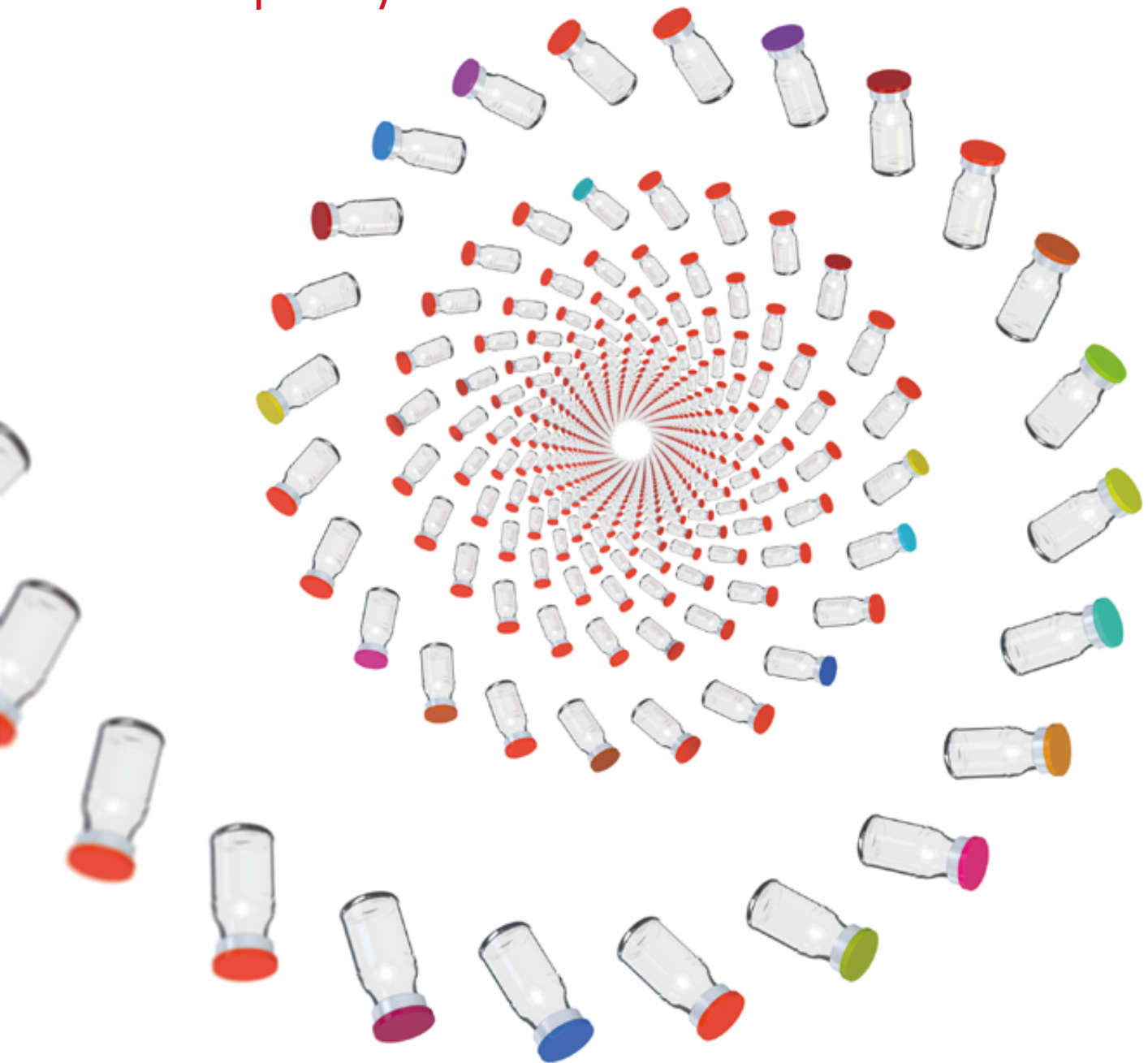


Company Portfolio



Antibiotice, an international company



- A portfolio that includes over 140 products of 12 therapeutic classes;
- 8 production lines for: sterile powders for injection, penicillin, capsules, non-penicillin capsules, cephalosporin capsules, tablets, ointments, creams and gels, suppositories, pessaries, active pharmaceutical ingredients produced by biosynthesis;
- An important manufacturer of anti-infective drugs, anti-inflammatory drugs, dermatologicals, gastrointestinals, cardiovasculars, oncology and nervous system drugs;
- Top manufacturer of Nystatin;
- Internationally acknowledged approvals and certificates: US FDA approval for Nystatin and sterile powders for injection, Certificate of Suitability to the European Pharmacopoeia (CoS) for Nystatin, Good Manufacturing Practice (GMP) certificate for all the manufacturing lines, Good Laboratory Practice (GLP), integrated Management System;
- The first European company WHO prequalified for essential anti-tuberculosis medicines;
- 70 products registered on the international markets;
- 120 partners in 72 countries all over the world;
- Modern in-house R&D center.

Complete generic product development **services:** from API to clinical trial



Authorized site for clinical,
bioanalytical and statistical services



Pharmaceutical development,
Regulatory Affairs, Pharmacovigilance



Active Pharmaceutical Ingredients

Human use

NYSTATIN (microfine powder)

Quality: EP 8 / BP 2015 / USP 36

Packing: cardboard boxes of 100 BOU Nystatin,
with 2 polyethylene bags of 50 BOU each

NYSTATIN (superfine powder)

Particle size: 90% < 10 μm , 100% < 15 μm

Quality: EP 8 / BP 2015 / USP 36

Packing: cardboard boxes of 50 BOU Nystatin,
with 1 polyethylene bag of 50 BOU

Veterinary use

NYSTATIN feed grade

Assay: min 1500 IU / mg

Quality: Antibiotice technical specification

Packing: cardboard boxes of 25 kg net,
with 1 polyethylene bag of 25 kg net

Rx Portfolio



A – Alimentary tract and metabolism

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
A02B – Drugs for peptic ulcer and gastro-oesophageal reflux disease					
1	OMEPRAZOL Atb® 20 mg	gastro-resistant capsules	omeprazolum	Box x 20 capsules	EU eCTD
2	RANITIDINE Atb® 150 mg	film coated tablets	ranitidinium	Box x 20 tablets Box x 1200 tablets	**
A07 – Antidiarrheals, intestinal antiinflammatory / antiinfective agents					
1	NYSTATIN Atb® 500 000 UI	film coated tablets	nystatinum	Box x 20 tablets Box x 1500 tablets	**

C – Cardiovascular System

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
C03 – Diuretics					
1	INDAPAMIDE Atb® 1.5 mg	prolonged release tablets	indapamidum	Box x 30 tablets	EU eCTD
C04 – Peripheral vasodilators					
1	NICERGOLINE Atb® 30 mg	film coated tablets	nicergolinum	Box x 30 tablets	EU eCTD
C05 – Vasoprotectives					
1	HEMORZON®	suppositories	tetracyclinum + hydrocortisoni acetat + benzocainum	Box x 6 suppositories Box x 12 suppositories	**
2	HEMORZON®	ointment	tetracyclinum + hydrocortisoni acetat + benzocainum	Box x 1 tube x 18 g	**
C07 – Beta Blocking Agents					
1	BISOTENS® 5 mg	film coated tablets	bisoprololi fumaras	Box x 30 tablets	**
2	BISOTENS® 10 mg	film coated tablets	bisoprololi fumaras	Box x 30 tablets	**
3	GLADYCOR® 6.25 mg	tablets	carvedilolum	Box x 30 tablets	**
4	GLADYCOR® 12.5 mg	tablets	carvedilolum	Box x 30 tablets	**
5	GLADYCOR® 25 mg	tablets	carvedilolum	Box x 30 tablets	**
6	NEBIVOLOL Atb® 5 mg	tablets	nebivololum	Box x 30 tablets	EU eCTD
7	NEBIVOLOL Atb® 10 mg	tablets	nebivololum	Box x 30 tablets	EU eCTD

C - Cardiovascular System

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
C08 – Calcium channel blockers					
1	ALMACOR® 5 mg	tablets	amlodipinum	Box x 30 tablets	EUeCTD
2	ALMACOR® 10 mg	tablets	amlodipinum	Box x 30 tablets	EUeCTD
C09 – Agents acting on the Renin-Angiotensin System					
1	CANDESARTAN Atb® 8 mg	tablets	candesartanum cilexetili	Box x 30 tablets	EU eCTD
2	CANDESARTAN Atb® 16 mg	tablets	candesartanum cilexetili	Box x 30 tablets	EU eCTD
3	LISINOPRIL Atb® 10 mg	tablets	lisinoprilum	Box x 20 tablets Box x 30 tablets	EU eCTD
4	LISINOPRIL Atb® 20 mg	tablets	lisinoprilum	Box x 10 tablets Box x 30 tablets	EU eCTD
5	LISINOPRIL Atb® 40 mg	tablets	lisinoprilum	Box x 10 tablets Box x 30 tablets	EU eCTD
6	RAMIPRIL Atb® 2.5 mg	tablets	ramiprilum	Box x 30 tablets	EU eCTD
7	RAMIPRIL Atb® 5 mg	tablets	ramiprilum	Box x 30 tablets	EU eCTD
8	RAMIPRIL Atb® 10 mg	tablets	ramiprilum	Box x 30 tablets	EU eCTD
C10 – Lipid modifying agent					
1	ROSUVASTATIN Atb® 5 mg	film coated tablets	rosuvastatinum	Box x 30 tablets	EU eCTD
2	ROSUVASTATIN Atb® 10 mg	film coated tablets	rosuvastatinum	Box x 30 tablets	EU eCTD
3	ROSUVASTATIN Atb® 20 mg	film coated tablets	rosuvastatinum	Box x 30 tablets	EU eCTD
4	ROSUVASTATIN Atb® 40 mg	film coated tablets	rosuvastatinum	Box x 30 tablets	EU eCTD

* Dossier with limited production and/or regulatory support

** Dossier available for some territories

D - Dermatologicals

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
D06 – Antibiotics and chemotherapeutics for dermatological use					
1	TETRACYCLINE Atb® 30mg/g	ointment	tetracyclini hydrochloridum	Box x 1 tube x 12 g	**
D07 – Corticosteroids, dermatological preparations					
1	EKARZIN® 0.5 mg/g	cream	betamethasonum	Box x 1 tube x 15 g	**
2	SAL-EKARZIN® 0.50 mg/30 mg/g	ointment	betamethasoni + acidum salicylicum	Box x 1 tube x 15 g	**
3	CLOBETASOL Atb® 0.50 mg/g	cream	clobetasol	Box x 1 tube x 25 g	**
4	CLOBETASOL Atb® 0.50 mg/g	ointment	clobetasol	Box x 1 tube x 25 g	**
5	CLO-EKARZIN® 0.50 mg/10 mg/g	cream	clotrimazolum + betamethasonum	Box x 1 tube x 15 g	**
6	FLUOCINOLONE N Atb® 0.25 mg/5 mg/g	ointment	fluocinoloni acetonidum + neomycini sulfas	Box x 1 tube x 18 g	**
7	HYDROCORTISONE Atb® 10 mg/g	ointment	hydrocortisonum	Box x 1 tube x 20 g	**
8	MOMETASONE Atb® 1 mg/g	cream	mometasoni furoas	Box x 1 tube x 15 g	**
9	MOMETASONE Atb® 1 mg/g	ointment	mometasoni furoas	Box x 1 tube x 15 g	**
10	NIDOFLOR®	cream	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Box x 1 tube x 15 g	**
11	TRIAMCINOLONE S Atb® 1 mg/30 mg/g	cream	triamcinoloni acetonidum + chlorquinaldolum	Box x 1 tube x 15 g	**

G - Genito-urinary system and sex hormones

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
G01 – Gynecological antiinfectives and antiseptics					
1	ZIFEX® DUO 500 mg/200 mg	pessaries	metronidazolum + clotrimazolum	Box x 7 pessaries Box x 14 pessaries	** Bibliographical Application
2	ZIFEX® COMPLEX	pessaries	nystatinum + neomycini sulfas + metronidazolum + hydrocortisoni acetat	Box x 7 pessaries Box x 14 pessaries	** Bibliographical Application
3	NYSTATIN Atb® 100 000 UI	pessaries	nystatinum	Box x 7 pessaries Box x 14 pessaries	** Bibliographical Application

J – Antiinfectives for systemic use

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use					
1	AMOXICILLIN Atb® 250 mg	capsules	amoxicillinum	Box x 20 capsules Box x 1000 capsules	EU eCTD
2	AMOXICILLIN Atb® 500 mg	capsules	amoxicillinum	Box x 10 capsules Box x 1000 capsules	EU eCTD
3	AMOXIPLUS® 1000 mg/200 mg	powder for injection/ infusion	amoxicillinum + acidum clavulanicum	Box x 1 vial Box x 50 vials Box x 100 vials	**
4	AMPICILLIN Atb® 250 mg	capsules	ampicillinum	Box x 20 capsules Box x 1000 capsules	**
5	AMPICILLIN Atb® 500 mg	capsules	ampicillinum	Box x 10 capsules Box x 1000 capsules	**
6	AMPICILLIN 250 mg	powder for injection	ampicillinum	Box x 1 vial Box x 100 vials	** US eCTD
7	AMPICILLIN 500 mg	powder for injection	ampicillinum	Box x 1 vial Box x 50 vials Box x 100 vials	** US eCTD
8	AMPICILLIN 1 g	powder for injection	ampicillinum	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	** US eCTD
9	AMPICILLIN 2 g	powder for injection	ampicillinum	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	** US eCTD
10	AMPIPLUS® 1000 mg/500 mg	powder for injection/ infusion	ampicillinum + sulbactamum	Box x 1 vial Box x 50 vials	** US eCTD
11	BENZYL PENICILLIN Atb® POTASSIUM 1 000 000 UI	powder for injection	benzylpenicillinum potassium	Box x 1 vial Box x 50 vials Box x 100 vials	*
12	BENZYL PENICILLIN Atb® SODIUM 400 000 UI	powder for injection	benzylpenicillinum sodium	Box x 1 vial Box x 50 vials Box x 100 vials	*
13	BENZYL PENICILLIN Atb® SODIUM 1 000 000 UI	powder for injection	benzylpenicillinum sodium	Box x 1 vial Box x 50 vials Box x 100 vials	*
14	CEFALEXINE Atb® 250 mg	capsules	cefalexinum	Box x 20 capsules Box x 1000 capsules	**
15	CEFALEXINE Atb® 500 mg	capsules	cefalexinum	Box x 10 capsules Box x 1000 capsules	**
16	CEFORAN® 500 mg	capsules	cefadroxilum	Box x 10 capsules Box x 1000 capsules	**
17	CEFORT® 250 mg	powder for injection/ infusion	ceftriaxonum	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**

* Dossier with limited production and/or regulatory support

** Dossier available for some territories

J – Antiinfectives for systemic use

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use					
18	CEFORT® 500 mg	powder for injection /infusion	ceftriaxonum	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
19	CEFORT® 1 g	powder for injection /infusion	ceftriaxonum	Box x 1 vial Box x 10 vials Box x 50 vials	**
20	CEFORT® 2 g	powder for injection /infusion	ceftriaxonum	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
21	CEFOTAXIME Atb® 1 g	powder for injection /infusion	cefotaximum	Box x 1 vial Box x 10 vials	**
22	CEFTAMIL® 1 g	powder for injection /infusion	ceftazidimum	Box x 1 vial Box x 10 vials Box x 50 vials	**
23	CEFTAMIL® 2 g	powder for injection /infusion	ceftazidimum	Box x 1 vial Box x 10 vials Box x 50 vials	**
24	CEFUROXIME Atb® 750 mg	powder for suspension(im) /injection (iv)	cefuroximum	Box x 1 vial Box x 10 vials Box x 100 vials	**
25	CEFUROXIME Atb® 1.5 g	powder for suspension(im) /injection (iv)	cefuroximum	Box x 1 vial Box x 10 vials Box x 50 vials	**
26	CIPRO QUIN® 500 mg	film coated tablets	ciprofloxacinum	Box x 10 tablets	*
27	COLISTIN Atb® 1 000 000 IU	powder for injection /infusion	colistimethatum sodium	Box x 10 vials Box x 50 vials Box x 100 vials Box x 150 vials	in-licensing
28	DOXYCYCLINE Atb® 100 mg	capsules	doxycyclinum	Box x 10 capsules Box x 1000 capsules	**
29	EFICEF® 100 mg	capsules	cefiximum	Box x 10 capsules Box x 1000 capsules	**
30	EFICEF® 200 mg	capsules	cefiximum	Box x 10 capsules Box x 1000 capsules	EU eCTD
31	ERYTHROMYCIN Atb® 200 mg	tablets	erythromycinum	Box x 20 tablets Box x 1500 tablets	*
32	FLUCLOXACILLIN Atb® 500 mg	powder for injection /infusion	flucloxacillinum	Box x 1 vial Box x 10 vials	EU eCTD
33	FLUCLOXACILLIN Atb® 1000 mg	powder for injection /infusion	flucloxacillinum	Box x 1 vial Box x 10 vials	EU eCTD
34	IMIPENEM/CILASTATIN Atb® 500/500 mg	powder for injection /infusion	imipenemum + cilastatinum	Box x 1 vial Box x 5 vials Box x 10 vials	in-licensing
35	LEVOFLOXACIN Atb® 250 mg	film coated tablets	levofloxacinum	Box x 10 tablets	EU eCTD
36	LEVOFLOXACIN Atb® 500 mg	film coated tablets	levofloxacinum	Box x 10 tablets	EU eCTD

J – Antiinfectives for systemic use

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use					
37	MEROPENEM Atb® 500 mg	powder for injection /infusion	meropenemum	Box x 1 vial Box x 10 vials Box x 50 vials	in-licensing
38	MEROPENEM Atb® 1000 mg	powder for injection /infusion	meropenemum	Box x 1 vial Box x 10 vials Box x 50 vials	in-licensing
39	NAFCILLIN 1 g	powder for injection	nafcillinum	Box x 10 vials	US eCTD
40	NAFCILLIN 2 g	powder for injection	nafcillinum	Box x 10 vials	US eCTD
41	NORFLOXACIN Atb® 400 mg	film coated tablets	norfloxacinum	Box x 20 tablets	EU eCTD
42	OXACILLIN Atb® 250 mg	capsules	oxacillinum	Box x 20 capsules Box x 100 capsules	**
43	OXACILLIN Atb® 500 mg	capsules	oxacillinum	Box x 10 capsules Box x 100 capsules	**
44	OXACILLIN Atb® 500 mg	powder for injection /infusion	oxacillinum	Box x 1 vial Box x 50 vials Box x 100 vials	*
45	OXACILLIN Atb® 1 g	powder for injection /infusion	oxacillinum	Box x 1 vial Box x 50 vials Box x 100 vials	*
46	PERASIN® 2 g/0.25 g	powder for infusion	piperacillinum + tazobactamum	Box x 1 vial Box x 10 vials	EU eCTD
47	PERASIN® 4 g/0.5 g	powder for infusion	piperacillinum + tazobactamum	Box x 1 vial Box x 10 vials	EU eCTD
48	ROCLARIN® 500 mg	film coated tablets	clarithromycinum	Box x 20 tablets	**
49	TETRACYCLINE Atb® 250 mg	capsules	tetracyclini hydrochloridum	Box x 20 capsules Box x 1000 capsules	**
50	TIGECYCLINE Atb® 50 mg	powder for infusion	tigecyclinum	Box x 1 vial Box x 10 vials	EU eCTD
51	ERTAPENEM Atb® 1 g	powder for concentrate for solution for infusion	ertapenem sodium	Box x 10 vials	EU eCTD

* Dossier with limited production and/or regulatory support

** Dossier available for some territories

J02 - Antimycotics for systemic use

1	CASPOFUNGIN Atb® 50 mg	powder for concentrate for solution for infusion	caspofunginum	Box x 1 vial	EU eCTD
2	CASPOFUNGIN Atb® 70 mg	powder for concentrate for solution for infusion	caspofunginum	Box x 1 vial	EU eCTD

J04 - Antimycobacterials

1	CYCLOSERINE Atb® 250mg	capsules	cycloserinum	Box x 50 capsules Box x 100 capsules	in-licensing
2	ETHAMBUTOL Atb® 250mg	film coated tablets	ethambutoli hydrochloridum	Box x 20 tablets Box x 1500 tablets	**
3	ETHAMBUTOL Atb® 400mg	film coated tablets	ethambutolum	Box x 20 tablets Box x 1500 tablets	**
4	ISONIAZID Atb® 100 mg	tablets	isoniazidum	Box x 20 tablets Box x 1500 tablets	**
5	ISONIAZID Atb® 300 mg	tablets	isoniazidum	Box x 30 tablets Box x 1500 tablets	**
6	PYRAZINAMIDE Atb® 500 mg	tablets	pyrazinamidum	Box x 20 tablets Box x 1500 tablets	**
7	SINERDOL® ISO	capsules	rifampicinum + isoniazidum	Box x 10 capsules Box x 1000 capsules	**
8	SINERDOL® 150 mg	capsules	rifampicinum	Box x 20 capsules Box x 1000 capsules	**
9	SINERDOL® 300 mg	capsules	rifampicinum	Box x 10 capsules Box x 1000 capsules	**

M – Musculo-skeletal system

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
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M01A – Antiinflammatory and antirheumatic products, non-steroids

1	ACECLOFEN®	suppositories	paracetamolium + diclofenacum natricum	Box x 6 suppositories Box x 12 suppositories	**
2	CLAFEN® 100 mg	suppositories	diclofenacum natricum	Box x 6 suppositories Box x 12 suppositories	**
3	INDOMETACIN Atb® 500 mg	suppositories	indometacinum	Box x 6 suppositories Box x 12 suppositories	**

N – Nervous system

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
N02 – Analgesics					
1	NOVOCALMIN® 500 mg	tablets	metamizolum natricum	Box x 10 tablets Box x 20 tablets Box x 1500 tablets	*
2	NOVOCALMIN® 300 mg	suppositories	metamizolum natricum	Box x 6 suppositories Box x 12 suppositories	*
N05C – Hipnotics and sedatives					
1	ZOLPIDEM Atb® 10 mg	tablets	zolpidemi tartras	Box x 10 tablets	**
N06A – Anti-depressants					
1	ZATINEX Atb® 30 mg	gastro-resistant capsules	duloxetine	Box x 28 capsules	in-licensing
2	ZATINEX Atb® 60 mg	gastro-resistant capsules	duloxetine	Box x 28 capsules	in-licensing
3	ESCITALOPRAM Atb® 5 mg	film coated tablets	escitalopramum	Box x 28 tablets	in-licensing
4	ESCITALOPRAM Atb® 10 mg	film coated tablets	escitalopramum	Box x 28 tablets	in-licensing
5	ESCITALOPRAM Atb® 15 mg	film coated tablets	escitalopramum	Box x 28 tablets	in-licensing
6	ESCITALOPRAM Atb® 20 mg	film coated tablets	escitalopramum	Box x 28 tablets	in-licensing
7	NOBIXAL® 12,5 mg	film coated tablets	tianeptinum natricum	Box x 1 tablet Box x 15 tablets Box x 30 tablets Box x 60 tablets Box x 90 tablets	in-licensing
N06D – Anti-dementia drugs					
1	MEMANTINA Atb® 10 mg	film coated tablets	memantinum	Box x 56 tablets	in-licensing
2	MEMANTINA Atb® 20 mg	film coated tablets	memantinum	Box x 56 tablets	in-licensing
3	MEMANTINA Atb® 5 mg + 10 mg + 15 mg + 20 mg	film coated tablets	memantinum	Combined box x 28 tablets	in-licensing
4	TUADIN® 10 mg	film coated tablets	donepezilum	Box x 30 tablets Box x 60 tablets Box x 90 tablets	in-licensing
N07- Other nervous system drugs					
No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
1	BETAHISTINE Atb® 8 mg	tablets	betahistinum	Box x 30 tablets	EU eCTD
2	BETAHISTINE Atb® 24 mg	tablets	betahistinum	Box x 30 tablets	EU eCTD

* Dossier with limited production and/or regulatory support

** Dossier available for some territories

V03AB – Antidotes

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
1	POTASSIUM IODIDE Atb® 65 mg	tablets	kalii iodidum	Box x 30 tablets	**

Over the Counter Portfolio



A – Alimentary tract and metabolism

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
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A03 – Drugs for functional gastrointestinal disorders

1	SPAVERIN® 40 mg	capsules	drotaverinum hydrochloridum	Box x 20 capsules Box x 1000 capsules	**
2	SPAVERIN® 80 mg	capsules	drotaverinum hydrochloridum	Box x 20 capsules Box x 1000 capsules	**

A06 – Drugs for constipation

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
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1	GLYCEROL SUPPOSITORIES for adults	suppositories	glycerolum	Box x 6 suppositories Box x 12 suppositories	**
2	GLYCEROL SUPPOSITORIES for children	suppositories	glycerolum	Box x 6 suppositories Box x 12 suppositories	**

B – Blood and blood forming organs

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
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B01 – Antithrombotic agents

1	ROMPIRIN® E 100 mg	gastro-resistant film coated tablets	acidum acetylsalicylicum	Box x 20 tablets Box x 30 tablets Box x 1500 tablets	EU CTD Bibliographical Application
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D – Dermatologicals

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
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D01 – Antifungals for dermatological use

1	CLOTRIMAZOLE Atb® 10 mg/g	cream	clotrimazolum	Box x 1 tube x 15 g Box x 1 tube x 35 g	**
2	NAFTIFINE Atb® 10 mg/g	cream	naftifini hydrochloridum	Box x 1 tube x 15 g	**
3	TAFICEN® 10 mg/g	cream	terbinafini hydrochloridum	Box x 1 tube x 15 g	**

D06 – Antibiotics and chemotherapeutics for dermatological use

1	CICATROL® 10 mg/g	cutaneous paste	sulfadiazinum argentum	Box x 1 tube x 20 g Box x 1 tube x 50 g Box x 1 tube x 100 g	EU CTD Bibliographical Application
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D07 – Corticosteroids, dermatological preparations

1	NEOPREOL® 2.5 mg/5 mg/g	ointment	prednisolonum + neomycini sulfas	Box x 1 tube x 40 g	*
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M – Musculo-skeletal system

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
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M01 – Antiinflammatory and antirheumatic products

1	IBUFEN® 200 mg	film coated tablets	ibuprofenum	Box x 10 tablets Box x 20 tablets Box x 30 tablets	**
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M02 – Topical products for joint and muscular pain

1	CLAFEN® 10 mg/g	cream	diclofenacum natricum	Box x 1 tube x 20 g Box x 1 tube x 40 g	**
2	CLAFEN® 10 mg/g	gel	diclofenacum natricum	Box x 1 tube x 40 g Box x 1 tube x 100 g	**
3	CLAFEN® 50 mg/g	gel	diclofenacum natricum	Box x 1 tube x 25 g Box x 1 tube x 45 g Box x 1 tube x 100 g	**
4	CLAFEN® 11.6 mg/g	gel	diclofenacum diethylaminum	Box x 1 tube x 40 g	**
5	SALIFORM® FORTE	cream	methyl salicylate + levomentholum	Box x 1 tube x 25 g Box x 1 tube x 100 g	**

N – Nervous System

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
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N02 – Analgesics

1	PARACETAMOL Atb® 125 mg	suppositories	paracetamolum	Box x 6 suppositories Box x 12 suppositories	EU CTD
2	PARACETAMOL Atb® 250 mg	suppositories	paracetamolum	Box x 6 suppositories Box x 12 suppositories	EU CTD

* Dossier with limited production and/or regulatory support

** Dossier available for some territories

V07AB - Solvents and diluting agents

No	Name of the product	Pharmaceutical form	Active substance	Packaging	File status
1	SODIUM CHLORIDE 9 mg/ml	solvent for parenteral use	natrii chloridum	Box x 5 ampoules Box x 10 ampoules Box x 240 ampoules	in-licensing
2	WATER FOR INJECTIONS	solvent for parenteral use	aqua ad injectabile	Box x 5 ampoules x 5 ml Box x 10 ampoules x 5 ml Box x 348 ampoules x 5 ml Box x 5 ampoules x 10 ml Box x 10 ampoules x 10 ml Box x 240 ampoules x 10 ml	in-licensing

Food supplements

No	Name of the product	Pharmaceutical form	Active substance	Packaging
1	EQUILIBRA®	capsules	magnesium + pyridoxini hydrochloridum	Box x 60 capsules
2	SILITHOR®	capsules	silibum + metionium + cysteinum	Box x 60 capsules
3	FLUXIV®	tablets	acidum ascorbicum + troxerutinum + diosminum + hesperidinum	Box x 60 tablets
4	SORISO®	tablets	rhodiola rosea + ocimum basilicum	Box x 60 tablets
5	SPRINTEN®	film coated tablets	Chondroitini natrii sulfas Acidum ascorbicum Zinc lactate dihydrate Glucosamine sulfate potassium chloride Acidum hyaluronicum (sodium salt)	Box x 60 tablets Box x 20 tablets
6	FEZIVIT C®	capsules	Acidum ascorbicum Iron (Ferronyl®) Zinc lactate dihydrate	Box x 10 capsules Box x 30 capsules Box x 60 capsules

Cosmetic products

No	Name of the product	Pharmaceutical form	Active substance	Packaging
1	CUTADEN®	cream	zinci oxidum + ichthammolum + hamamelis virginiana extractum	Box x 1 tube x 40 g
2	CUTADEN® Bebe	cream	zinci oxidum + ichthammolum + titanium dioxide + Vital ET™	Box x 1 tube x 40 g
3	FLUXIV®	cream	troxerutinum d-panthenolum	Box x 1 tube x 40 g Box x 1 tube x 100 g
4	TINERO®	gel	nicotinamidum	Box x 1 tube x 20 g Box x 1 tube x 40 g

DISCLAIMER: These products cannot be supplied into countries in which their use and/or commercialization may be in conflict with existing IP rights of a third party. In any event, any use and/or commercialization in breach of the above will be made under your sole and/or the final buyer's responsibility (as the case may be) and you will keep us fully indemnified and harmless from any claims and consequences arising out of such commercialization, use and breach.

Research and Development offers various Analytical Services, Formulation Services and Pharmaceutical Services, such as:

- Characterization of the reference drug product
- Development and validation of in-house analytical methods
- Design of pharmaceutically equivalent drug products, in different pharmaceutical forms:
 - conventional, modified release or gastro-resistant tablets
 - hard gelation capsules
 - semi-solid products (gel, cream, ointment)
 - suppositories and pessaries
 - powders for solutions/suspensions for injection (beta-lactam penicillins in low volumes)
- Monitoring drug product quality through stability studies
- Design of the manufacturing process
- Pilot technology for research and development

Complete clinical services

- GCP inspected & GLP certified bioanalytical laboratory
- GMP certified facility for IMP packaging as single dose
- Complete clinical services, from protocol development to file application, bioanalytical and biostatistics services, respecting the latest international regulations in the pharmaceutical field
- Comprehensive range of clinical development and consulting services for Phase I and bioequivalence studies
- Bioanalytical services: development and validation of LC-MS/MS, LC-UV and LC-fluorescence bioassays, quantification of multi-analytes, metabolites, pro-drugs, light and temperature-sensitive compounds in various biological matrixes, transfer and revalidation of the Sponsor method
- Statistical services/statistical analysis
- Dissolution profiles and dissolution tests, biowaiver type studies, respecting latest European legislation

Regulatory expertise

- Differentiated regulatory strategies for EU, USA and other countries for drug product and active substances sustained by Regulatory Affairs experts
- Full regulatory support for eCTD, NeeS and paper submission
- Multilingual packaging and labeling
- Maintenance of regulatory approvals throughout their lifecycle

Pharmacovigilance Services

Contact data

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