

Antibiotice

Science and soul



Product Portfolio

international
reliable partner

Top manufacturer for
Penicillin Sterile powders for injection

Worldwide leader
for **Nystatin API**

State-of-the-Art
facility for
Topical products

Certified CRO
(Contract Research Organization)



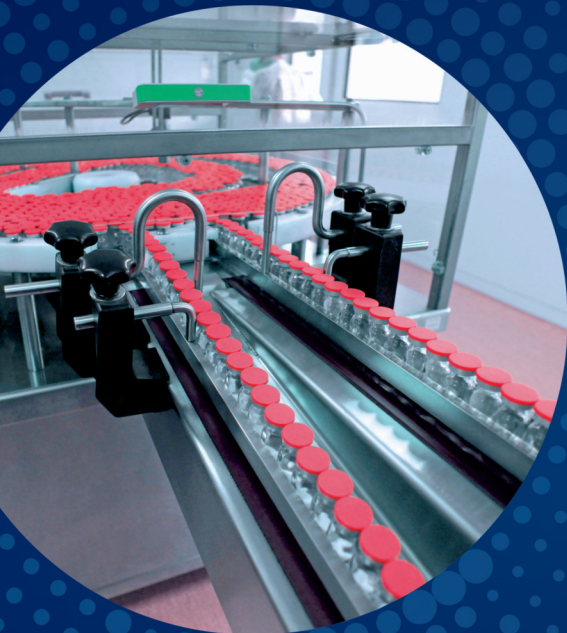
Antibiotice, an international company



- Company with a long tradition in manufacturing finished dosage forms: sterile powders for injections, capsules, tablets, ointments, gels, creams, suppositories, pessaries.
- Complex portfolio for **Hospital & Partners** consisting of more than 30 products for Hospital use: penicillin, penicillin in combination with beta-lactams inhibitors, cephalosporins and carbapenems; updated dossiers for beta-lactam products.
- Worldwide Leading Manufacturer of **Nystatin API**, vertically integrating several finished dosage forms using Nystatin.
- Developed a various portfolio of products intended to improve the **Quality of Life** such as food supplements, dermato-cosmetics, women's health products and medicines designed for the health of cardiovascular, osteo-articular and digestive systems.
- Upcoming launches of creams, ointments and pessaries supported by clinical studies, focused on **Dermatology** and **Women's Health**.
- Internationally acknowledged certifications and approvals:
 - 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 manufacturing sites;
 - Good Laboratory Practice (GLP) for Bioanalytical Laboratories from Clinical Trials Center;
 - Integrated Management System (ISO 9001, ISO 14001, ISO 45001)
- In-house Clinical Trials Center – a full-service Contract Research Organisation (CRO) authorised by the National Agency for Medicines and Medical Devices of Romania, specialized in Phase I Clinical Trials and Bioequivalence (BE) studies.
- 4 Representative Offices in Vietnam (Hanoi), Ukraine (Kiev), Serbia (Novi Sad) and Moldova (Chisinau).
- +60 Products registered in different international markets.



European Top Manufacturer for Penicillin Sterile Powders for Injection



- › Ampicillin and Sulbactam
- › Amoxicillin and Clavulanic Acid
- › Ampicillin Sodium
- › Nafcillin Sodium
- › Flucloxacillin Sodium
- › Piperacillin and Tazobactam
- › Benzylpenicillin
- › Benzathine Benzylpenicillin



SUSTAINABLE
DEVELOPMENT GOALS



J - Antiinfectives for systemic use

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use						
1	AMOXICILLIN Atb® 250 mg	Rx	capsules	amoxicillin trihydrate	Box x 20 capsules Box x 1000 capsules	EU eCTD
2	AMOXICILLIN Atb® 500 mg	Rx	capsules	amoxicillin trihydrate	Box x 10 capsules Box x 1000 capsules	EU eCTD
3	AMOXIPLUS® 1000 mg/200 mg	Rx	powder for injection/ infusion	amoxicillin sodium + potassium clavulanate	Box x 1 vial Box x 25 vials Box x 50 vials Box x 100 vials	EU eCTD
4	AMPICILLIN Atb® 250 mg	Rx	powder for injection	ampicillin sodium	Box x 1 vial Box x 100 vials	EU eCTD US eCTD
5	AMPICILLIN Atb® 500 mg	Rx	powder for injection	ampicillin sodium	Box x 1 vial Box x 50 vials Box x 100 vials	EU eCTD US eCTD
6	AMPICILLIN Atb® 1000 mg	Rx	powder for injection	ampicillin sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	EU eCTD US eCTD
7	AMPICILLIN Atb® 2000 mg	Rx	powder for injection	ampicillin sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	EU eCTD US eCTD
8	AMPIPLUS® 1000 mg/500 mg	Rx	powder for injection/ infusion	ampicillin sodium + sulbactam sodium	Box x 1 vial Box x 10 vials Box x 25 vials Box x 50 vials	EU eCTD US eCTD
9	AMPIPLUS® 2000 mg/1000 mg	Rx	powder for injection/ infusion	ampicillin sodium + sulbactam sodium	Box x 10 vials	US eCTD
10	BENZYLPENICILLIN POTASSIUM Atb® 1 000 000 IU	Rx	powder for injection	benzylpenicillin potassium	Box x 1 vial Box x 50 vials Box x 100 vials	*
11	BENZYLPENICILLIN SODIUM Atb® 400 000 IU	Rx	powder for injection	benzylpenicillin sodium	Box x 1 vial Box x 50 vials Box x 100 vials	*
12	BENZYLPENICILLIN SODIUM Atb® 1 000 000 IU	Rx	powder for injection	benzylpenicillin sodium	Box x 1 vial Box x 50 vials Box x 100 vials	*
13	CEFALEXINE Atb® 250 mg	Rx	capsules	cefalexin monohydrate	Box x 20 capsules Box x 1000 capsules	**
14	CEFALEXINE Atb® 500 mg	Rx	capsules	cefalexin monohydrate	Box x 10 capsules Box x 1000 capsules	**
15	CEFORAN® 500 mg	Rx	capsules	cefadroxil monohydrate	Box x 10 capsules Box x 1000 capsules	**

* Dossier with limited production and/or regulatory support

** Dossier available for certain territories

J – Antiinfectives for systemic use

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use						
16	CEFORT® 250 mg	Rx	powder for injection/ infusion	ceftriaxone sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
17	CEFORT® 500 mg	Rx	powder for injection /infusion	ceftriaxone sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
18	CEFORT® 1 g	Rx	powder for injection /infusion	ceftriaxone sodium	Box x 1 vial Box x 10 vials Box x 50 vials	**
19	CEFORT® 2 g	Rx	powder for injection /infusion	ceftriaxone sodium	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
20	CEFOTAXIME Atb® 1 g	Rx	powder for injection /infusion	cefotaxime sodium	Box x 1 vial Box x 10 vials	**
21	CEFTAMIL® 1 g	Rx	powder for injection /infusion	ceftazidime pentahydrate	Box x 1 vial Box x 10 vials Box x 50 vials	**
22	CEFTAMIL® 2 g	Rx	powder for injection /infusion	ceftazidime pentahydrate	Box x 1 vial Box x 10 vials Box x 50 vials	**
23	CEFUROXIME Atb® 750 mg	Rx	powder for suspension (im) /injection (iv)	cefuroxime sodium	Box x 1 vial Box x 10 vials Box x 100 vials	**
24	CEFUROXIME Atb® 1.5 g	Rx	powder for suspension (im) /injection (iv)	cefuroxime sodium	Box x 1 vial Box x 10 vials Box x 100 vials	**
25	COLISTIN Atb® 1 000 000 IU	Rx	powder for injection /infusion	colistimethate sodium	Box x 1 vial Box x 50 vials Box x 100 vials	in-licensing
26	EFICEF® 100 mg	Rx	capsules	cefixime	Box x 10 capsules Box x 1000 capsules	**
27	EFICEF® 200 mg	Rx	capsules	cefixime	Box x 10 capsules Box x 1000 capsules	EU eCTD
28	ERTAPENEM Atb® 1 g	Rx	powder for concentrate for solution for infusion	ertapenem sodium	Box x 10 vials	in-licensing
29	FLUCLOXACILLIN Atb® 500 mg	Rx	powder for injection /infusion	flucloxacillin sodium	Box x 1 vial Box x 10 vials	EU eCTD
30	FLUCLOXACILLIN Atb® 1000 mg	Rx	powder for injection /infusion	flucloxacillin sodium	Box x 1 vial Box x 10 vials	EU eCTD
31	IMIPENEM/CILASTATIN Atb® 500 mg/500 mg	Rx	powder for infusion	imipenem monohydrate + cilastatin sodium	Box x 1 vial Box x 5 vials Box x 10 vials	in-licensing

J – Antiinfectives for systemic use

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use						
32	LEVOFLOXACIN Atb® 250 mg	Rx	film coated tablets	levofloxacin	Box x 10 tablets	EU eCTD
33	LEVOFLOXACIN Atb® 500 mg	Rx	film coated tablets	levofloxacin	Box x 10 tablets	EU eCTD
34	MEROPENEM Atb® 500 mg	Rx	powder for injection /infusion	meropenem trihydrate	Box x 1 vial Box x 10 vials Box x 50 vials	in-licensing
35	MEROPENEM Atb® 1000 mg	Rx	powder for injection /infusion	meropenem trihydrate	Box x 1 vial Box x 10 vials Box x 50 vials	in-licensing
36	MOLDAMIN® 1200000 IU	Rx	powder for suspension for injection	benzathine benzylpenicillin	Box x 1 vial Box x 10 vials Box x 50 vials	**
37	NAFCILLIN 1 g	Rx	powder for injection	nafcillin sodium	Box x 10 vials	US eCTD
38	NAFCILLIN 2 g	Rx	powder for injection	nafcillin sodium	Box x 10 vials	US eCTD
39	OXACILLIN Atb® 500 mg	Rx	powder for injection /infusion	oxacillin sodium monohydrate	Box x 1 vial Box x 50 vials Box x 100 vials	*
40	OXACILLIN Atb® 1 g	Rx	powder for injection /infusion	oxacillin sodium monohydrate	Box x 1 vial Box x 50 vials Box x 100 vials	*
41	PERASIN® 2 g/0.25 g	Rx	powder for infusion	piperacillin sodium + tazobactam sodium	Box x 1 vial Box x 10 vials	EU eCTD
42	PERASIN® 4 g/0.5 g	Rx	powder for infusion	piperacillin sodium + tazobactam sodium	Box x 1 vial Box x 10 vials	EU eCTD
43	ROCLARIN® 500 mg	Rx	film coated tablets	clarithromycin	Box x 20 tablets	**
44	TIGECYCLINE Atb® 50 mg	Rx	powder for infusion	tigecycline	Box x 1 vial Box x 10 vials	in-licensing
45	VANCOMYCIN Atb® 500 mg	Rx	powder for infusion	vancomycin	Box x 1 vial Box x 10 vials	in-licensing
46	VANCOMYCIN Atb® 1000 mg	Rx	powder for infusion	vancomycin	Box x 1 vial Box x 10 vials	in-licensing

* Dossier with limited production and/or regulatory support

** Dossier available for certain territories

New State-of-the-Art Manufacturing Facility for Topical Products

More than 65 years of Experience
in Manufacturing Topical Products



Dedicated Manufacturing Lines:

- ▶ 2 lines for ointments, creams and gels
- ▶ 2 lines for suppositories and pessaries

SUSTAINABLE
DEVELOPMENT GOALS





4 dedicated manufacturing lines:

- **2 manufacturing lines for ointments, creams, gels and cutaneous pastes**

Aluminum tubes, ø 13–35 mm; fill volume: from 6 to 150 g of product;

Plastic/laminated tubes, ø 25–35 mm; fill volume: from 100 to 150 g of product;
with the possibility of expansion to smaller weights.

- **2 manufacturing lines for suppositories and pessaries**

Suppositories, fill volume: from 1 to 2.3 g, using PVC/PE and Alu/PE foil as primary packaging;

Pessaries, fill volume: from 2.5 to 2.8 g, using PVC/PE foil as primary packaging



550 Tons – Yearly production capacity

- energetic efficiency- System BMS/EMS
(Building Management System/Environment Monitoring System)
- flexibility in operation
- optimization of energy consumption
- state-of-the-art-technology
- real-time proces control
- product quality safety
- multiple monitoring parameters



Worldwide presence through our partnerships, conducting successful audits and cooperations with International Authorities.



Product development in our Research & Development Center with the possibility to manufacture in our new state-of-the-art facility.

D - Dermatologicals

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
D01 – Antifungals for dermatological use						
1	CLOTRIMAZOLE Atb® 10 mg/g	OTC	cream	clotrimazole	Box x 1 tube x 15 g Box x 1 tube x 35 g	EU eCTD Q3 2023
D07 – Corticosteroids, dermatological preparations						
1	EKARZIN® 0.5 mg/g	Rx	cream	betamethasone dipropionate	Box x 1 tube x 15 g	*
2	CLO-EKARZIN® 0.50 mg/10 mg/g	Rx	cream	clotrimazole + betamethasone dipropionate	Box x 1 tube x 15 g	*
3	CLOBETASOL Atb® 0.50 mg/g	Rx	cream	clobetasol propionate	Box x 1 tube x 25 g	EU eCTD Q4 2024
4	CLOBETASOL Atb® 0.50 mg/g	Rx	ointment	clobetasol propionate	Box x 1 tube x 25 g	EU eCTD Q3 2024
5	FLUOCINOLONE N Atb® 0.25 mg/5 mg/g	Rx	ointment	fluocinolone acetonide + neomycin sulfate	Box x 1 tube x 18 g	*
6	MOMETASONE Atb® 1 mg/g	Rx	cream	mometasone furoate	Box x 1 tube x 15 g	EU eCTD Q3 2024
7	MOMETASONE Atb® 1 mg/g	Rx	ointment	mometasone furoate	Box x 1 tube x 15 g	EU eCTD Q3 2024
8	NIDOFLOR®	Rx	cream	nystatin + neomycin sulfate + triamcinolone acetonide	Box x 1 tube x 15 g	*
9	SAL-EKARZIN® 0.50 mg/30 mg/g	Rx	ointment	betamethasone dipropionate + salicylic acid	Box x 1 tube x 15 g	*

M – Musculo-skeletal system

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
M01A – Antiinflammatory and antirheumatic products, non-steroids						
1	ACECLOFEN®	Rx	suppositories	paracetamol + diclofenac sodium	Box x 6 suppositories Box x 12 suppositories	EU eCTD
2	CLAFEN® 100 mg	Rx	suppositories	diclofenac sodium	Box x 6 suppositories Box x 12 suppositories	**
M02 – Topical products for joint and muscular pain						
1	CLAFEN® 10 mg/g	OTC	gel	diclofenac sodium	Box x 1 tube x 40 g Box x 1 tube x 100 g	**
2	CLAFEN® 50 mg/g	OTC	gel	diclofenac sodium	Box x 1 tube x 25 g Box x 1 tube x 45 g Box x 1 tube x 100 g	**
3	DICLOFENAC DIETHYLAMINE 11.6 mg/g	OTC	gel	diclofenac diethylamine	Box x 1 tube x 40 g	**

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Topical products



SUSTAINABLE DEVELOPMENT **GOALS**



A - Alimentary tract and metabolism

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
A02 - Drugs for acid related disorders						
1	NOVOGAST® 20 mg	OTC	gastro-resistant capsules	omeprazole	Box x 10 capsules	EU eCTD
2	OMEPRAZOL Atb® 20 mg	Rx	gastro-resistant capsules	omeprazole	Box x 20 capsules	EU eCTD
A06 - Drugs for constipation						
1	GLYCEROL SUPPOSITORIES for adults	OTC	suppositories	glycerol	Box x 6 suppositories Box x 12 suppositories	**
2	GLYCEROL SUPPOSITORIES for children	OTC	suppositories	glycerol	Box x 6 suppositories Box x 12 suppositories	**
A07 - Antidiarrheals, intestinal antiinflammatory / antiinfective agents						
1	NYSTATIN Atb® 500 000 IU	Rx	film coated tablets	nystatin	Box x 20 tablets Box x 1500 tablets	**

B - Blood and blood forming organs

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
B01 - Antithrombotic agents						
1	ROMPIRIN® E 100 mg	OTC	gastro-resistant film coated tablets	acethylsalicylic acid	Box x 20 tablets Box x 50 tablets Box x 1500 tablets	EU eCTD Bibliographical Application

C - Cardiovascular System

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
C03 - Diuretics						
1	INDAPAMIDE Atb® 1.5 mg	Rx	prolonged release tablets	indapamide	Box x 30 tablets	EU eCTD
C04 - Peripheral vasodilators						
1	NICERGOLINE Atb® 30 mg	Rx	film coated tablets	nicergoline	Box x 30 tablets	EU eCTD
C07 - Beta Blocking Agents						
1	BISOTENS® 5 mg	Rx	film coated tablets	bisoprolol fumarate	Box x 30 tablets	EU eCTD
2	BISOTENS® 10 mg	Rx	film coated tablets	bisoprolol fumarate	Box x 30 tablets	EU eCTD
3	GLADYCOR® 6.25 mg	Rx	tablets	carvedilol	Box x 30 tablets	EU eCTD
4	GLADYCOR® 12.5 mg	Rx	tablets	carvedilol	Box x 30 tablets	EU eCTD
5	GLADYCOR® 25 mg	Rx	tablets	carvedilol	Box x 30 tablets	EU eCTD
6	NOLET® 5 mg	Rx	tablets	nebivolol hydrochloride	Box x 30 tablets	EU eCTD

C – Cardiovascular System

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
C08 – Calcium channel blockers						
1	ALMACOR® 5 mg	Rx	tablets	amlodipine besilate	Box x 30 tablets	**
2	ALMACOR® 10 mg	Rx	tablets	amlodipine besilate	Box x 30 tablets	**
C09 – Agents acting on the Renin-Angiotensin System						
1	CANDESARTAN Atb® 8 mg	Rx	tablets	candesartan cilexetil	Box x 30 tablets	EU eCTD
2	CANDESARTAN Atb® 16 mg	Rx	tablets	candesartan cilexetil	Box x 30 tablets	EU eCTD
3	LISINOPRIL Atb® 10 mg	Rx	tablets	lisinopril dihydrate	Box x 20 tablets Box x 30 tablets	EU eCTD
4	LISINOPRIL Atb® 20 mg	Rx	tablets	lisinopril dihydrate	Box x 10 tablets Box x 30 tablets	EU eCTD
5	LISINOPRIL Atb® 40 mg	Rx	tablets	lisinopril dihydrate	Box x 10 tablets Box x 30 tablets	EU eCTD
6	RAMIPRIL Atb® 2.5 mg	Rx	tablets	ramipril	Box x 30 tablets	EU eCTD
7	RAMIPRIL Atb® 5 mg	Rx	tablets	ramipril	Box x 30 tablets Box x 60 tablets Box x 90 tablets	EU eCTD
8	RAMIPRIL Atb® 10 mg	Rx	tablets	ramipril	Box x 30 tablets Box x 60 tablets Box x 90 tablets	EU eCTD
C10 – Lipid modifying agent						
1	ROSUVASTATIN Atb® 5 mg	Rx	film coated tablets	rosuvastatin calcium	Box x 30 tablets	EU eCTD
2	ROSUVASTATIN Atb® 10 mg	Rx	film coated tablets	rosuvastatin calcium	Box x 30 tablets	EU eCTD
3	ROSUVASTATIN Atb® 20 mg	Rx	film coated tablets	rosuvastatin calcium	Box x 30 tablets	EU eCTD
4	ROSUVASTATIN Atb® 40 mg	Rx	film coated tablets	rosuvastatin calcium	Box x 30 tablets	EU eCTD

G – Genito-urinary system and sex hormones

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
G01 – Gynecological antiinfectives and antiseptics						
1	NYSTATIN Atb® 100 000 IU	Rx	pessaries	nystatin	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application
2	ZIFEX® DUO	Rx	pessaries	metronidazole + clotrimazole	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application
3	ZIFEX® COMPLEX	Rx	pessaries	nystatin + neomycin sulfate + metronidazole + hydrocortisone acetate	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application

* Dossier with limited production and/or regulatory support

** Dossier available for certain territories

J - Antiinfectives for systemic use

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
J04 – Antimycobacterials						
1	CYCLOSERINE Atb® 250mg	Rx	capsules	cycloserine	Box x 50 capsules Box x 100 capsules	in-licensing
2	ETHAMBUTOL Atb® 250mg	Rx	film coated tablets	ethambutol hydrochloride	Box x 20 tablets Box x 1500 tablets	**
3	ETHAMBUTOL Atb® 400mg	Rx	film coated tablets	ethambutol hydrochloride	Box x 20 tablets Box x 1500 tablets	**
4	ETHIONAMIDE Atb® 250 mg	Rx	film coated tablets	ethionamide	Box x 100 tablets	in-licensing
5	ISONIAZID Atb® 100 mg	Rx	tablets	isoniazid	Box x 20 tablets Box x 1500 tablets	**
6	ISONIAZID Atb® 300 mg	Rx	tablets	isoniazid	Box x 30 tablets Box x 1500 tablets	**
7	PYRAZINAMIDE Atb® 500 mg	Rx	tablets	pyrazinamide	Box x 20 tablets Box x 1500 tablets	**
8	SINERDOL® ISO	Rx	capsules	rifampicin + isoniazid	Box x 10 capsules Box x 1000 capsules	**
9	SINERDOL® 150 mg	Rx	capsules	rifampicin	Box x 20 capsules Box x 1000 capsules	**
10	SINERDOL® 300 mg	Rx	capsules	rifampicin	Box x 10 capsules Box x 1000 capsules	**

N - Nervous system

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
N02 – Analgesics						
1	PARACETAMOL Atb® 125 mg	OTC	suppositories	paracetamol	Box x 6 suppositories Box x 12 suppositories	**
2	PARACETAMOL Atb® 250 mg	OTC	suppositories	paracetamol	Box x 6 suppositories Box x 12 suppositories	**
N07 – Other nervous system drugs						
1	BETAHISTINE Atb® 8 mg	Rx	tablets	betahistine dihydrochloride	Box x 30 tablets	EU eCTD
2	BETAHISTINE Atb® 24 mg	Rx	tablets	betahistine dihydrochloride	Box x 30 tablets	EU eCTD

V03AB – Antidotes

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
1	POTASSIUM IODIDE Atb® 65 mg	Rx	tablets	potassium iodide	Box x 30 tablets	**

Food suppliments

No	Name of the product	Pharmaceutical form	Active substance	Packaging
1	EQUILIBRA®	capsules	magnesium + pyridoxine hydrochloride	Box x 60 capsules
2	FEZIVIT C®	capsules	ascorbic acid + iron + zinc lactate dihydrate	Box x 10 capsules Box x 30 capsules Box x 60 capsules
3	FLUXIV®	tablets	ascorbic acid + troxerutin + diosmine + hesperidine	Box x 60 tablets
4	IMUNOFIX®	tablets	Organic vitamin C (as Hibiscus sabdariffa flower extract standardized in at least 5% Vitamin C) Echinacea aerial part extract (Echinacea purpurea) standardized in at least 4% polyphenols Echinacea root extract (Echinacea angustifolia) standardized in at least 4% echinacosides Zinc dihydrate lactate	Box x 10 tablets Box x 30 tablets Box x 60 tablets
5	LEJER®	capsules	Senna leaf extract (Cassia senna) standardized in at least 20% sennosides Rhubarb root extract (Rheum palmatum) standardized in at least 5% rhein Ginger root extract (Zingiber officinale) standardized in at least 5% gingerols Organic vitamin C (as Hibiscus sabdariffa flower extract standardized in at least 5% vitamin C)	Box x 10 capsules Box x 30 capsules Box x 60 capsules
6	SILITHOR®	capsules	silybum + methionine + L-cysteine	Box x 60 capsules
7	SimbiFlora Complex	capsules	Lactobacillus + Bifidobacterium + Selenium + Vitamin E	Box x 10 capsules
8	SimbiFlora Forte	capsules	Lactobacillus + Bifidobacterium and fructooligosaccharide fibers + Vitamin D3 + Zinc	Box x 20 capsules
9	SimbiFlora Kids	oral powder	Lactobacillus sp and Bifidobacterium sp + inulin fibers + Vitamin D3	Box x 10 sachets
10	SORISO®	tablets	rhodiola rosea ("golden root") + ocimum basilicum (basil)	Box x 60 tablets
11	SORISO Activ ®	capsules	Polygonum cuspidatum root extract, standardized in at least 50% trans-resveratrol Ginkgo biloba leaf extract standardized in at least 24% flavonoid glycosides and 6% terpene lactones Vitamin B6 (pyridoxine hydrochloride)	Box x 10 capsules Box x 30 capsules Box x 60 capsules
12	SORISO Memo®	capsules	Guarana seeds extract (Paullinia cupana) standardized in at least 22% caffeine Niacine L-glutamine Taurine Tryptophan	Box x 10 capsules Box x 30 capsules Box x 60 capsules
13	SPRINTEN®	tablets	chondroitin sulfate sodium + ascorbic acid + zinc lactate dihydrate + glucosamine sulfate potassium chloride + hyaluronic acid (sodium salt)/sodium hyaluronate	Box x 60 tablets Box x 20 tablets

Cosmetic products

No	Name of the product	Pharmaceutical form	Active substance	Packaging
1	CUTADEN®	cream	zinc oxide + ichthammol + hamamelis virginiana extract	Box x 1 tube x 40 g
2	CUTADEN® Bebe	cream	zinc oxide + ichthammol + titanium dioxide + Vital ET™	Box x 1 tube x 40 g
3	FLUXIV®	cream	troxerutin + d-panthenol	Box x 1 tube x 40 g Box x 1 tube x 100 g
4	TINERO®	gel	nicotinamide	Box x 1 tube x 40 g Box x 1 tube x 100 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.

Pipeline

J - Antiinfectives for systemic use

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
J01 – Antibacterials for systemic use						
1	AMPIPLUS® 3 g	Rx	powder for solution for injection/infusion	ampicillin sodium, sulbactam sodium	Box x 1 vial Box x 10 vials Box x 25 vials	Q4 2022
2	EFICEF® 400 mg	Rx	capsules	cefixime	Box x 10 capsules	Q1 2024
3	RIFAXIMINE 200 mg	Rx	capsules	rifaximine	Box x 30 capsules	Q4 2024

A - Alimentary tract and metabolism

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
A02 – Drugs for acid related disorders						
1	FAMOTIDINE/CALCIUM CARBONATE/ MAGNESIUM HYDROXIDE 10 mg/800 mg/165 mg	Rx	tablets	famotidine, calcium carbonate, magnesium hydroxide	Box x 10 tablets	Q2 2025

D - Dermatologicals

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
N01 – Anesthetics, local						
1	PRILOCAINE/LIDOCAINE 25 mg/25 mg/g	Rx	cream	prilocaine, lidocaine hydrochloride	Box x 1 tube x 5 g Box x 1 tube x 30 g	Q1 2025
D06 – Dermatologicals, antibiotics for topical use						
2	NEOMICINE/ZINC BACITRACINE 5000 IU/250 IU/g	OTC	ointment	neomycin sulfate + bacitracin zinc	Box x 1 tube x 20 g	Q4 2022 Bibliographical application

G - Genito-urinary system and sex hormones

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
N01 - Anesthetics, local						
1	ZIFEX TRIO	Rx	pessaries	metronidazole, nystatin, neomycin sulfate	Box x 7 pessaries Box x 14 pessaries	Q1 2024

M - Musculo-skeletal system

No	Name of the product	Rx/OTC	Pharmaceutical form	Active substance	Packaging	File status
M01 - Antiinflammatory and antirheumatic products						
1	NAPROXEN/ESOMEPRAZOLE 500 mg/20 mg	OTC	modified-release tablets	naproxen sodium, esomeprazole magnesium	Box x 10 tablets	Q1 2025

Worldwide Leading Manufacturer of **Nystatin API**

- Nystatin standard
- Nystatin micronized
- Nystatin compacted

Manufactured Since 1970

Pharmaceutical Forms using Nystatin API:

-  oral suspensions
-  tablets, capsules
-  creams, ointments, topical powders
-  pessaries



SUSTAINABLE DEVELOPMENT GOALS



- **Nystatin ATB contains a single polymorphic form, polymorph A.**
- **Polymorphic form A (dihydrate) is maintained after the Micronisation, which proves to be a repeatable, stable and reproducible process (stable crystal, which comes after Micronisation).**
- **Purity and polymorphic stability ensures a clear advantage in the formulation of finished products, regardless of their pharmaceutical form (tablets, topical products or suspensions).**

NYSTATIN MICRONIZED

Quality according current edition of the EP/USP Pharmacopoeia

- **PARTICLE SIZE** 90% of particles no more than 10 μm
100% of particles no more than 15 μm
- **PACKING** polyethylene bags inserted in triple layer PET/Al/PE bags and placed in cardboard boxes
- **STORAGE** store below 25°C in original packaging, protected from light
- **SHELF LIFE** 36 months

NYSTATIN NON-MICRONIZED

Quality according current edition of the EP/USP Pharmacopoeia

- **PARTICLE SIZE** 90% of particles no more than 45 μm
- **PACKING** polyethylene bags inserted in triple layer PET/Al/PE bags and placed in cardboard boxes
- **STORAGE** store below 25°C in original packaging, protected from light
- **SHELF LIFE** 36 months



Fully Integrated Certified Contract Research Organization

- > Phase I/Bioequivalence Studies
- > The CTC features a fully integrated organization in one site and includes:



**20 years of experience
in Developing and
Conducting Clinical Trials**

**SUSTAINABLE
DEVELOPMENT GOALS**



The **Clinical Trials Center (CTC)** is a full service Contract Research Organization (CRO) authorized by the National Agency for Medicines and Medical Devices of Romania, which performs phase I clinical trials and bioequivalence (BE) studies.

For more than **20 years**, many generic pharmaceutical companies have registered their products all over the world using our expertise in conducting clinical studies on Antibiotice's site.

The **CTC** features a fully integrated organizational structure located on one site, consisting of:

- a GCP inspected Clinical Unit;
- a GLP certified Analytical Unit – state-of-the-art laboratory equipment and technologies;
- a GMP certified IMP secondary packaging line (for the packaging and labeling of investigational medicinal products).

Complete clinical services from protocol development to dossier application, in compliance with the latest international regulations

➤ Client-oriented CRO

- We offer facilities and services for conducting Phase I clinical trials and bioequivalence studies for many medicinal products covering a broad range of therapeutic areas
- We offer expert advice (scientific, regulatory) taking into account the current regulations for the biopharmaceutical industry and the requirements of regulatory agencies
- We provide innovative and high – quality services, with integrity and reliability
- We provide Quality Guarantee; our Internal Quality Assurance and Quality Control Units develop well-designed sets of Standard Operating Procedures (SOPs) and ensure that clinical trials are conducted according to the Harmonized European Legislation (ICH), Integrated Management System (ISO 9001, ISO 14001 ISO 45001), Good Clinical and Laboratory Practice guidelines and Helsinki Declaration

Services offered by Antibiotice's Clinical Trials Center

> Medical writing and Study Management

- Clinical Project management
- Protocol development
- Informed consent forms, including local language ICFs (prepared and reviewed by the relevant country)
- Clinical trial reports according to the ICH E3 and eCTD format
- Regulatory applications and submissions to the EC & regulatory authorities
- Archiving of essential trial documents and all the related data
- Safety reporting and other pharmacovigilance activities related to the clinical studies
- GCP monitoring and auditing

> Bioanalytical services:

- Development and validation of LC-MS/MS, LC-UV and LC fluorescence bioanalysis
- Quantification of multianalytes. metabolites, prodrugs, light and temperature – sensitive compounds in various biological matrixes
- Transfer and revalidation of Sponsor method
- GLP auditing and quality control

> Data Management & Biostatistics

- CRF design
- Database Design and Validation
- Medical Coding
- Data Entry
- Biostatistics
- PK; PK/PD analysis



Contact data

Out & In-Licensing

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Dosage Forms Export

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Middle East, Africa)

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