

Let's create
The Future Together!

at
Antibiotice



Product Portfolio



**Integrated CDMO and
CMO facilities**

Let's create
The Future Together!

”For seven decades, Antibiotice has been pursuing its destiny of a reliable API and finished generics manufacturer.

Through our business plan *The Future Together*, we have designed our development perspective up until 2030. We start the way to our future destination using our experience, current and future manufacturing capacities, developing generic medicines from Molecule to Market.

We invite you to join us in building **The Future Together!**”

Antibiotice Team

Who we are:

- ➔ **US-FDA & EU GMP worldwide leading manufacturer of Nystatin APIs**, also Nystatin API produced by Antibiotice is the reference standard certified by the United States Pharmacopeia
- ➔ **EU GMP & US-FDA top manufacturer for penicillins-powders for injection:** penicillins and penicillins in combination with beta-lactam inhibitors
- ➔ **20+ years presence in the US market** with Nystatin API and penicillin powders for injection
- ➔ One of the most modern **European manufacturing facilities for topical products:** ointments, creams, gels, suppositories and pessaries
- ➔ **Manufacturing facilities for various pharmaceutical solid oral forms:** penicillin capsules, cephalosporin capsules, non-penicillin capsules, tablets, film-coated tablets, MR/SR tablets
- ➔ **Diversified and customer-focused portfolio of products intended to improve the quality of life:** food supplements, dermocosmetics, medical devices
- ➔ **Fully integrated, certified contract research organization (CRO)**, specialized in Phase I Clinical Trials and Bioequivalence studies
- ➔ **Presence in 70+ countries worldwide**

J – Antiinfectives for systemic use

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
J01 – Antibacterials for systemic use							
1	amoxicillin trihydrate	Amoxicillin Atb® 250 mg	capsules	Amoxil 500 mg Smithkline-Beecham	Rx	Box x 20 capsules Box x 1000 capsules	EU eCTD
2	amoxicillin trihydrate	Amoxicillin Atb® 500 mg	capsules	Amoxil 500 mg Smithkline-Beecham	Rx	Box x 10 capsules Box x 1000 capsules	EU eCTD
3	ampicillin trihydrate	Ampicillin Atb® 200 mg	capsules	Pentrexyl, BMS	Rx	Box x 20 capsules Box x 1000 capsules	**
4	ampicillin trihydrate	Ampicillin Atb® 500 mg	capsules	Pentrexyl, BMS	Rx	Box x 10 capsules Box x 1000 capsules	**
5	amoxicillin and clavulanic acid	Amoxiplus® 1000 mg/200 mg	powder for injection/infusion	Augmentin, GSK	Rx	Box x 1 vial Box x 10 vials Box x 25 vials Box x 50 vials	EU eCTD
6	ampicillin sodium sulbactam sodium	Ampiplus® 1000 mg/500 mg	powder for injection	Unasyn, Pfizer	Rx	Box x 1 vial Box x 10 vials Box x 25 vials Box x 50 vials	EU eCTD
7	ampicillin sodium sulbactam sodium	Ampiplus® 2000 mg/1000 mg	powder for injection	Unasyn, Pfizer	Rx	Box x 1 vial Box x 10 vials	EU eCTD
8	ampicillin sodium	Ampicillin Atb® 250 mg	powder for injection	Doktacillin, Meda AB	Rx	Box x 1 vial Box x 50 vials	EU eCTD
9	ampicillin sodium	Ampicillin Atb 500 mg	powder for injection	Doktacillin, Meda AB	Rx	Box x 1 vial Box x 50 vials	EU eCTD
10	ampicillin sodium	Ampicillin Atb® 1000 mg	powder for injection	Doktacillin, Meda AB	Rx	Box x 1 vial Box x 50 vials	EU eCTD
11	ampicillin sodium	Ampicillin Atb® 2000 mg	powder for injection	Doktacillin, Meda AB	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	EU eCTD
12	ampicillin sodium	Ampicillin for Injection USP 250 mg	powder for injection	Ampicillin for injection USP Sandoz	Rx	Box x 1 vial Box x 50 vials	USeCTD
13	ampicillin sodium	Ampicillin for Injection USP 500 mg	powder for injection	Ampicillin for injection USP Sandoz	Rx	Box x 1 vial Box x 50 vials	USeCTD
14	ampicillin sodium	Ampicillin for Injection USP 1 g	powder for injection	Ampicillin for injection USP Sandoz	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	USeCTD
15	ampicillin sodium	Ampicillin for Injection USP 2 g	powder for injection	Ampicillin for injection USP Sandoz	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	USeCTD
16	ampicillin sodium sulbactam sodium	Ampicillin and Sulbactam for Injection USP 1.5 g	powder for injection	Unasyn for injection USP, Pfizer	Rx	Box x 1 vial Box x 10 vials	USeCTD
17	ampicillin sodium sulbactam sodium	Ampicillin and Sulbactam for Injection USP 3 g	powder for injection	Unasyn for injection USP, Pfizer	Rx	Box x 10 vials	USeCTD

** Dossier availability depending on country legislation

J – Antiinfectives for systemic use

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
J01 – Antibacterials for systemic use							
18	benzathine benzylpenicillin	Moldamin® 1200000 IU	powder for suspension for injection		Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
19	doxycycline	Doxycycline Atb® 100 mg	capsules	Vibramycin, Pfizer	Rx	Box x 10 capsules Box x 1000 capsules	**
20	cephalexin monohydrate	Cephalexin Atb® 250 mg	capsules	Keflex 500mg, Flynn Pharma	Rx	Box x 20 capsules Box x 1000 capsules	EU eCTD
21	cephalexin monohydrate	Cephalexin Atb® 500 mg	capsules	Keflex 500mg, Flynn Pharma	Rx	Box x 10 capsules Box x 1000 capsules	EU eCTD
22	cephadroxil monohydrate	Ceforan® 500 mg	capsules	Duracef ,BMS	Rx	Box x 10 capsules Box x 1000 capsules	EU eCTD
23	ceftriaxone sodium	Cefort® 250 mg, 500 mg	powder for injection /infusion	Rocephin, Hofmann La Roche	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
24	ceftriaxone sodium	Cefort® 1 g, 2 g	powder for injection /infusion	Rocephin, Hofmann La Roche	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
25	cefotaxime sodium	Cefotaxime Atb® 1 g	powder for injection /infusion	Claforan, Lepetit	Rx	Box x 1 vial Box x 10 vials	**
26	ceftazidime pentahydrate	Ceftamil ® 1 g, 2 g	powder for injection /infusion	Fortum, Glaxo	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
27	cefuroxime sodium	Cefuroxime Atb® 750 mg, 1.5 g	powder for suspension (im) /injection (iv)	Zinacef, GSK	Rx	Box x 1 vial Box x 10 vials	**
28	colistimethate sodium	Colistin Atb® 1 000 000 IU	powder for injection /infusion		Rx	Box x 1 vial Box x 50 vials	in-licensing
29	cefixime	Eficef® 100 mg	capsules	Oroken, Aventis Cefixoral, Menarini	Rx	Box x 10 capsules Box x 1000 capsules	**
30	cefixime	Eficef® 200 mg	capsules	Oroken, Aventis Cefixoral, Menarini	Rx	Box x 10 capsules Box x 1000 capsules	EU eCTD
31	cefixime	Eficef® 400 mg	capsules	Oroken, Aventis Cefixoral, Menarini	Rx	Box x 10 capsules	EU eCTD
32	clarithromycin	Roclarin® 500 mg	film-coated tablets	Klacid, Viatris	Rx	Box x 20 tablets	**
33	cycloserine	Cycloserine Atb® 250mg	capsules	Seromycin, Ely Lilly	Rx	Box x 50 capsules Box x 100 capsules	in-licensing
34	ertapenem sodium	Ertapenem Atb® 1 g	powder for concentrate for solution for infusion	Invanz, Merck Sharp& Dohme	Rx	Box x 10 vials	**
35	ethambutol hydrochloride	Ethambutol Atb® 250 mg, 400 mg	film coated tablets	Myambutol, Wyeth	Rx	Box x 20 tablets Box x 1500 tablets	**

** Dossier availability depending on country legislation

J - Antiinfectives for systemic use

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
J01 – Antibacterials for systemic use							
36	ethionamide	Ethionamide Atb® 250 mg	film coated tablets	Trecator ,Wyeth	Rx	Box x 100 tablets	in-licensing
37	flucloxacillin sodium	Flucloxacillin Atb® 500 mg	powder for injection	Floxapen, Aurobindo	Rx	Box x 1 vial Box x 10 vials	EU eCTD
38	flucloxacillin sodium	Flucloxacillin Atb® 1000 mg	powder for injection	Floxapen, Aurobindo	Rx	Box x 1 vial Box x 10 vials	EU eCTD
39	imipenem monohydrate +cilastatin sodium	Imipenem/Cilastatin Atb® 500 mg/500 mg	powder for infusion	Tienam, MSD	Rx	Box x 1 vial Box x 5 vials Box x 10 vials	in-licensing
40	isoniazid	Isoniazid Atb® 100 mg, 300 mg	tablets	Isozid, Fatol	Rx	Box x 20 tablets Box x 30 tablets Box x 1500 tablets	**
41	levofloxacin	Levofloxacin Atb 250 mg	film-coated tablets	Tavanic 500 mg, Sanofi Aventis	Rx	Box x 10 tablets	EU eCTD
42	levofloxacin	Levofloxacin Atb 500 mg	film-coated tablets	Tavanic 500 mg, Sanofi Aventis	Rx	Box x 10 tablets	EU eCTD
43	meropenem trihydrate	Meropenem Atb® 500 mg, 1000 mg	powder for injection /infusion	Merrem, Pfizer	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
44	nafcillin sodium	Nafcillin for Injection USP 1 g	powder for injection	Nafcillin for Injection USP, Sandoz	Rx	Box x 10 vials	USeCTD
45	nafcillin sodium	Nafcillin for Injection USP 2 g	powder for injection	Nafcillin for Injection USP, Sandoz	Rx	Box x 10 vials	USeCTD
46	oxacillin sodium monohydrate	Oxacillin Atb® 250 mg	capsules		Rx	Box x 20 capsules Box x 1000 capsules	**
47	oxacillin sodium monohydrate	Oxacillin Atb® 500 mg	capsules		Rx	Box x 10 capsules Box x 1000 capsules	**
48	oxacillin sodium monohydrate	Oxacillin Atb® 500 mg	powder for injection /infusion		Rx	Box x 1 vial Box x 50 vials	*
49	oxacillin sodium monohydrate	Oxacillin Atb® 1 g	powder for injection /infusion		Rx	Box x 1 vial Box x 50 vials	*
50	piperacillin sodium tazobactam sodium	Perasin® 2.5 g	powder for solution for infusion	Tazocin, Pfizer	Rx	Box x 1 vial Box x 10 vials	EU eCTD
51	piperacillin sodium tazobactam sodium	Perasin® 4.5 g	powder for solution for infusion	Tazocin, Pfizer	Rx	Box x 1 vial Box x 10 vials	EU eCTD
52	pyrazinamide	Pyrazinamide Atb® 500 mg	tablets	Zinamide, MSD	Rx	Box x 20 tablets Box x 1500 tablets	**
53	rifampicin + isoniazid	Sinerdol® ISO	capsules		Rx	Box x 10 capsules Box x 1000 capsules	**
54	rifampicin	Sinerdol® 150 mg, 300 mg	capsules		Rx	Box x 10 capsules Box x 20 capsules Box x 1000 capsules	**
55	tigecycline	Tigeclycin Atb® 50 mg	powder for infusion	Tygacil, Pfizer	Rx	Box x 1 vial Box x 10 vials	in-licensing

* Dossier with limited production and/or regulatory support

** Dossier availability depending on country legislation

C – Cardiovascular System

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
C07- Beta Blocking Agents							
1	bisoprolol fumarate	Bisotens® 5 mg	film-coated tablets	Concor, Merck	Rx	Box x 30 tablets	EU eCTD
2	bisoprolol fumarate	Bisotens® 10 mg	film-coated tablets	Concor, Merck	Rx	Box x 30 tablets	EU eCTD
3	carvedilol	Gladycor® 6.25 mg	tablets	Dilatrend, Roche	Rx	Box x 30 tablets	EU eCTD
4	carvedilol	Gladycor® 12.5 mg	tablets	Dilatrend, Roche	Rx	Box x 30 tablets	EU eCTD
5	carvedilol	Gladycor® 25 mg	tablets	Dilatrend, Roche	Rx	Box x 30 tablets	EU eCTD
6	nebivolol hydrochloride	Nolet® 5 mg	tablets	Nebilet, Berlin Chemie	Rx	Box x 30 tablets	EU eCTD
C08 – Calcium channel blockers							
1	amlodipine besilate	Almacor® 5 mg	tablets	Norvasc, Pfizer	Rx	Box x 30 tablets	**
2	amlodipine besilate	Almacor® 10 mg	tablets	Norvasc, Pfizer	Rx	Box x 30 tablets	**
C09 – Agents acting on the Renin-Angiotensin System							
1	candesartan cilexetil	Candesartan Atb® 8 mg	tablets	Atacand, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
2	candesartan cilexetil	Candesartan Atb® 16 mg	tablets	Atacand, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
3	lisinopril dihydrate	Lisinopril Atb® 10 mg	tablets	Zestril, Astra Zeneca	Rx	Box x 20 tablets Box x 30 tablets	EU eCTD
4	lisinopril dihydrate	Lisinopril Atb® 20 mg	tablets	Zestril, Astra Zeneca	Rx	Box x 10 tablets Box x 30 tablets	EU eCTD
5	lisinopril dihydrate	Lisinopril Atb® 40 mg	tablets	Zestril, Astra Zeneca	Rx	Box x 10 tablets Box x 30 tablets	EU eCTD
6	ramipril	Ramipril Atb® 2.5 mg	tablets	Tritace, Sanofi	Rx	Box x 30 tablets	EU eCTD
7	ramipril	Ramipril Atb® 5 mg	tablets	Tritace, Sanofi	Rx	Box x 30 tablets Box x 60 tablets Box x 90 tablets	EU eCTD
8	ramipril	Ramipril Atb® 10 mg	tablets	Tritace, Sanofi	Rx	Box x 30 tablets Box x 60 tablets Box x 90 tablets	EU eCTD
C10 – Lipid modifying agents							
1	rosuvastatin calcium	Rosuvastatin Atb® 5 mg	film-coated tablets	Crestor, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
2	rosuvastatin calcium	Rosuvastatin Atb® 10 mg	film-coated tablets	Crestor, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
3	rosuvastatin calcium	Rosuvastatin Atb® 20 mg	film-coated tablets	Crestor, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
4	rosuvastatin calcium	Rosuvastatin Atb® 40 mg	film-coated tablets	Crestor, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD

** Dossier availability depending on country legislation

B – Blood and blood forming organs

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
B01 – Antithrombotic agents							
1	acethylsalicylic acid	Rompirin® 100 mg	gastro-resistant film-coated tablets	Aspirin Cardio, Bayer	OTC	Box x 20 tablets Box x 50 tablets Box x 1500 tablets	EU eCTD

A – Alimentary tract and metabolism

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
A02 – Drugs for acid related disorders							
1	omeprazole	Omeprazol Atb® 20 mg	gastro-resistant capsules		Rx	Box x 20 capsules	EU eCTD
2	omeprazole	Novogast® 20 mg	gastro-resistant capsules		OTC	Box x 10 capsules	EU eCTD
A03 – Drugs for functional gastrointestinal disorders							
1	drotaverine hydrochloride	Spaverin® 40 mg	capsules	No-spa, Chinoin	OTC	Box x 20 capsules	**
2	drotaverine hydrochloride	Spaverin® 80 mg	capsules	No-spa, Chinoin	OTC	Box x 20 capsules	**
A06 – Drugs for constipation							
1	glycerol	Glycerol suppositories for adults	suppositories		OTC	Box x 6 suppositories Box x 12 suppositories	**
2	glycerol	Glycerol suppositories for children	suppositories		OTC	Box x 6 suppositories Box x 12 suppositories	**
A07 – Antidiarrheals, intestinal antiinflammatory / antiinfective agents							
1	nystatin	Nystatin Atb® 500 000 IU	film-coated tablets		Rx	Box x 20 tablets Box x 1500 tablets	**

N – Nervous system

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
N02 – Analgesics							
1	paracetamol	Paracetamol Atb® 125 mg	suppositories		OTC	Box x 6 suppositories Box x 12 suppositories	**
2	paracetamol	Paracetamol Atb® 250 mg	suppositories		OTC	Box x 6 suppositories Box x 12 suppositories	**
N07- Other nervous system drugs							
1	betahistine dihydrochloride	Betahistine Atb® 8 mg	tablets	Betaserc, Abbot	Rx	Box x 30 tablets	EU eCTD
2	betahistine dihydrochloride	Betahistine Atb® 24 mg	tablets	Betaserc, Abbot	Rx	Box x 30 tablets	EU eCTD

** Dossier availability depending on country legislation

D - Dermatologicals

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
D01 – Antifungals for dermatological use							
1	clotrimazole	Clotrimazol Atb® 10 mg/g	cream	Canesten, Bayer	OTC	Box x 1 tube x 15 g Box x 1 tube x 20 g Box x 1 tube x 35 g	EU eCTD Hybrid application
D06 – Dermatologicals, antibiotics for topical use							
1	neomycin sulfate + bacitracin zinc	Zinba®5000 IU/ 250 IU/g	ointment	Baneocin, Sandoz	OTC	Box x 1 tube x 5 g Box x 1 tube x 20 g	EUeCTD Hybrid application
D07 – Corticosteroids, dermatological preparations							
1	betamethasone dipropionate	Ekarzin® 0.5 mg/g	cream		Rx	Box x 1 tube x 15 g	*
2	betamethasone dipropionate + salicylic acid	Sal-Ekarzin® 0.50 mg/30 mg/g	ointment		Rx	Box x 1 tube x 15 g	*
3	clotrimazole + betamethasone dipropionate	Clo-Ekarzin® 0.50 mg/10 mg/g	cream		Rx	Box x 1 tube x 15 g	*
4	clobetasol propionate	Clobetasol Atb® 0.50 mg/g	cream		Rx	Box x 1 tube x 25 g	**
5	clobetasol propionate	Clobetasol Atb® 0.50 mg/g	ointment		Rx	Box x 1 tube x 25 g	**
6	fluocinolone acetonide + neomycin sulfate	Fluocinolone N Atb® 0.25 mg/5 mg/g	ointment		Rx	Box x 1 tube x 18 g	*
7	mometasone furoate	Mometasone Atb® 1 mg/g	cream		Rx	Box x 1 tube x 15 g	**
8	mometasone furoate	Mometasone Atb® 1 mg/g	ointment		Rx	Box x 1 tube x 15 g	**
9	nystatin + neomycin sulfate +triamcinolone acetonide	Nidoflor®	cream		Rx	Box x 1 tube x 15 g	*

V03AB – Antidotes

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
1	potassium iodide	Potassium iodine ® 65 mg	tablets		Rx	Box x 30 tablets	**

* Dossier with limited production and/or regulatory support
** Dossier availability depending on country legislation

State-of-the-Art Production Facility for Topical Products



Fully Integrated CRO



Ointments, Creams,
Gels, Suppositories,
Pessaries



Flexible business model



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

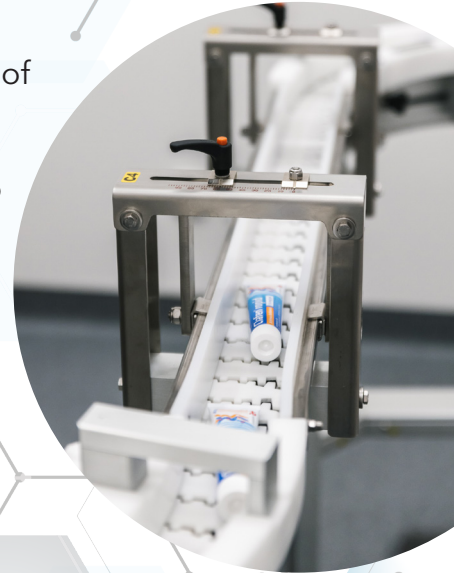
- energetic efficiency- System BMS/EMS (Building Management System/Environment Monitoring System)
- flexibility in operation
- optimization of energy consumption
- state-of-the-art technology
- real-time process control
- product quality safety
- multiple monitoring parameters



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.



M – Musculo-skeletal system

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
M01A – Antiinflammatory and antirheumatic products, non-steroids							
1	paracetamol + diclofenac sodium	Aceclofen®	suppositories		Rx	Box x 6 suppositories Box x 12 suppositories	**
2	diclofenac sodium	Clafen® 100 mg	suppositories		Rx	Box x 6 suppositories Box x 12 suppositories	**
M02 – Topical products for joint and muscular pain							
1	diclofenac diethylamine	Clafen® rapid 11.6 mg/g	gel	Voltaren, GSK	OTC	Box x 1 tube x 40 g	EU eCTD Bibliographical Application
2	diclofenac sodium	Clafen® 10 mg/g	gel		OTC	Box x 1 tube x 40 g Box x 1 tube x 100 g	**
3	diclofenac sodium	Clafen® forte 50 mg/g	gel		OTC	Box x 1 tube x 25 g Box x 1 tube x 45 g Box x 1 tube x 100 g	**

G - Genito-urinary system and sex hormones

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
G01 – Gynecological antiinfectives and antiseptics							
1	metronidazole + clotrimazole	Zifex® Duo	pessaries		Rx	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application
2	nystatin	Nystatin Atb® 100 000 IU	pessaries		Rx	Box x 7 pessaries Box x 14 pessaries	EU eCTD Bibliographical Application
3	nystatin + neomycin sulfate +metronidazole + hydrocortisone acetate	Zifex® Complex	pessaries		Rx	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application

** Dossier availability depending on country legislation

Cosmetic products (according to EU legislation)

No	Active substance	Brand name	Pharmaceutical form	Packaging
1	d-panthenol + urea + tocopherol (vitamin E) + phytoceramides + Avena Sativa Kernel Oil	Cutaden® Repair	cream	Box x 1 tube x 50 ml
2	niacinamide + dexpanthenol(nicotinamide)	Tinero®	gel	Box x 1 tube x 40 g Box x 1 tube x 15 g
3	tea tree oil+ niacinamide (nicotinamide) + lactic acid +salicylic acid + kaolin + Chamomilla Recutita Flower Extract	Tinero® TT Pure	purifying mask	Box x 1 tube x 50 ml
4	tea tree oil + niacinamide (nicotinamide) + salicylic acid	Tinero® TT Quick	cream	Box x 1 tube x 8 ml
5	tea tree oil + niacinamide (nicotinamide) + d-panthenol + lactic acid + salicylic acid + tocopherol (vitamin E)	Tinero® TT Clean	foaming gel	Box x 1 tube x 50 ml
6	tea tree oil + niacinamide (nicotinamide) + sodium hyaluronate + ceramides + Avena Sativa Kernel Flour, Avena Sativa Kernel Oil + tocopherol (vitamin E)	Tinero® TT Drop	cream, moisturizer	Box x 1 tube x 50 ml
7	troxerutin + d-panthenol	Fluxiv®	cream	Box x 1 tube x 20 g Box x 1 tube x 40 g Box x 1 tube x 100 g
8	panthenol + Jojoba Oil + Sweet Almond Oil + Shea butter + tocopherol (vitamin E) + zinc oxide	Cutaden® Bebe	cream	Box x 1 tube x 50 ml
9	zinc oxide + ichthammol +hamamelis virgiana extract	Cutaden®	cream	Box x 1 tube x 35 ml



Nutriensa®

Food supplements - Nutriensa Line (according to Romanian legislation)

No	Active substance	Brand name	Pharmaceutical form	Packaging	Therapeutic class
1	ascorbic acid + iron + zinc lactate dihydrate	Fezivit C®	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	health of skin, hair, nails
2	bifidobacterium animalis ssp lactis BL-G101 +Bifidobacterium longum ssp longum BL-G301 +Bifidobacterium longum ssp infantis BI-G201 + Lactobacillus acidophilus LA-G80 + Lactobacillus plantarum Lp-G18 +Lactobacillus rhamnosus Lr-G14 +Lactobacillus paracasei LPc-G110 +Lactobacillus reuteri LR-G100 +Inulin +Vitamin D3 (Cholecalciferol)	Simbiflora Kids	sachets	Box x 10 sachets Box x 20 sachets	microbiome, immunity
3	bifidobacterium bifidum BB-G90 +Bifidobacterium animalis ssp lactis BL-G101 +Bifidobacterium breve BB-G95 lactobacillus acidophilus LA-G80 + lactobacillus plantarum Lp-G18 + lactobacillus rhamnosus Lr-G14 + lactobacillus paracasei LPc-G110 + lactobacillus gasseri LG-G1+FOS (fructo-oligo-zaharide)+ zinc gluconate +vitamin D3 (Cholecalciferol)	Simbiflora Forte	capsules	Box x 10 capsules Box x 20 capsules	microbiome, immunity
4	bifidobacterium breve BB-G95+ bifidobacterium bifidum BB-G90+ bifidobacterium animalis ssp lactis BL-G101+ bifidobacterium longum ssp longum BL-G301+ bifidobacterium longum ssp infantis BI-G201+ lactobacillus plantarum Lp-G18 +lactobacillus rhamnosus Lr-G14 + lactobacillus delbrueckii ssp bulgaricus LB-G40 +lactobacillus casei LC-G11 +lactobacillus salivarius LS-G60 +lactobacillus helveticus LH-G51 +FOS (fructo-oligo-zaharide) + selenium enriched yeast + vitamin E (dl- α -tocopheryl acetate)	Simbiflora Complex	capsules	Box x 10 capsules Box x 20 capsules	microbiome, immunity
5	D-mannose +cranberry fruit extract (vaccinium macrocarpon) standardized in 25% proanthocyanidins (PAC tip A) + zinc lactate dihydrate	Urexpert®	film-coated tablets	Box x 10 film-coated tablets Box x 20 film-coated tablets	genitourinary system health
6	fish oil 1000 mg (600/ 150 EPA/ DHA) + vitamin E acetate (DL- α - tocopheryl acetate) + coenzyme Q10 + lycopene oil 6%	Tri Oli®	soft capsules	Box x 4 soft capsules Box x 15 soft capsules Box x 30 soft capsules	heart health
7	guarana seeds extract (paullinia cupana) standardized in at least 22% caffeine + vitamin B3 (Niacine) + L- glutamine +taurine + tryptophan	Soriso® Energy	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	central nervous system health
8	magnesi u dihydrate + vitamin B6 (pyridoxine hydrochloride)	Equilibra®	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	supporting metabolism
9	magnesium malate trihydrate + magnesium bisglycinate + vitamin B6 (pyridoxine hydrochloride)	Equilibra® Plus	film-coated tablets	Box x 10 film-coated tablets Box x 30 film-coated tablets	supporting metabolism
10	organic vitamin C as hibiscus flower extract (hibiscus sabdariffa) 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	Imunofix®	film-coated tablets	Box x 10 film-coated tablets Box x 30 film-coated tablets Box x 60 film-coated tablets	supporting immunity system



Nutriensa®

Food supplements - Nutriensa Line (according to Romanian legislation)

No	Active substance	Brand name	Pharmaceutical form	Packaging	Therapeutic class
11	Pancreatin (protease, amylase + lipase) + Pineapple stem extract (Ananas comosus L.) + Ginger root extract (Zingiber officinale) standardized in 5% gingerols + alpha-galactosidase + lactase	Enzistim®	gastro-resistant tablets	Box x 4 gastro-resistant tablets Box x 15 gastro-resistant tablets	alimentary tract and metabolism
12	polygonum cuspidatum root extract standardized in at least 50% trans-resveratrol+ ginkgo biloba leaves extract standardized in at least 24% ginkgoflavonoids and 6% lactone terpenes + Vitamin B6 (pyridoxine hydrochloride)	Soriso® Activ	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	central nervous system health
13	Red Clover aerial parts extract (Trifolium pratense L) standardized in 40% isoflavones + Flax Seed Extract (Linum usitatissimum L.) standardized in 20% lignans + Vitamin B6 (pyridoxine hydrochloride)	Lumiria®	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	genitounirary system and sex hormones
14	rhodiola or "golden root" extract (rhodiola rosea) standardized in at least 3% rosavine and 1% salidroside + basil extract (ocimum basilicum) standardized in at least 2% ursolic acid	Soriso®	tablets	Box x 10 tablets Box x 30 tablets Box x 60 tablets	central nervous system health
15	Saw Palmetto fruit extract (Serenoa repens) standardized in at least 45% fatty acids + Pumpkin Seed (Cucurbita pepo) standardized in at least 25% + Zinc dihydrate lactate	Urexpert® Pro	film-coated tablets	Box x 10 film-coated tablets Box x 30 film-coated tablets Box x 60 film-coated tablets	genitounirary system and sex hormones
16	senna leaf extract (Cassia angustifolia) standardized in at least 20% sennosides + rhubarb root extract (rheum palmatum) standardized in atleast 5% rhein + ginger root extract (zingiber o-ffcinale) standardized in atleast 5% gingerols + organic vitamin C as hibiscus flower extract (Hibiscus sabdariffa) standardized in at least 5% vitamin C	Lejer®	capsules	Box x 10 capsules Box x 20 capsules	health of the digestive system
17	silymarin seeds extract (silybum marianum) standardized in at least 80% silymarin + L-methionine + L-cysteine	Silithor®	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	liver health
18	troxerutin + diosmine + hesperidine + vitamin C (ascorbic acid)	Fluxiv®	film-coated tablets	Box x 60 tablets	peripheral circulation health
19	Valerian root extract (Valeriana officinalis L.) standardized in at least 0.8% valerenic acids + L-Theanine + Melatonin	Soriso® Luna	capsules	Box x 10 capsules Box x 20 capsules Box x 30 capsules	nervous system
20	yellow tablet chondroitin sulfate sodium + ascorbic acid + zinc lactate dihydrate white tablet glucosamine sulfate potassium chloride + hyaluronic acid (sodium salt)/sodium hyaluronate	Sprinten®	film-coated tablets	Box x 20 film-coated tablets (1 blister x 10 yellow film-coated tablets + 1 blister x 10 white film-coated tablets) Box x 60 film-coated tablets (3 blisters x 10 yellow film-coated tablets + 3 blister x 10 white film-coated tablets)	joint health

Fully Integrated Certified Contract Research Organization



20 years of experience
in Developing and
Conducting Clinical Trials

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.

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

- a GCP certified Clinical Unit for Phase I clinical trials and bioequivalence studies;
- a GLP certified Analytical Unit - state-of-the-art laboratory equipment and technologies;
- a GMP certified IMP secondary packaging line.

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

Services offered by Antibiotice's Clinical Trials Center:

- **Medical writing & Study Management**
- **Bioanalytical services**
- **Data Management & Biostatistics**
- **Research and Development**
 - Reverse engineering of the reference drug product
 - Development and validation of in-house analytical methods
 - Design of generic medicines, in different pharmaceutical forms:
 - conventional, modified release or gastro-resistant tablets
 - hard gelatin capsules
 - gels, creams, ointments
 - suppositories and pessaries
 - powders for solutions/suspensions for injection
 - solutions for injection
 - Monitoring drug product through stability studies
 - Design of the manufacturing process
 - Pilot technology for research and development
- **Regulatory expertise for EU, US and other countries for API's and drug products**
- **Pharmacovigilance Services**

Pipeline

J – Antiinfectives for systemic use

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
J01 – Antibacterials for systemic use							

1	rifaximine	Rifaximine 200 mg	capsules	Normix 200 mg Alfasigma	Rx	Box x 30 capsules	Q2 2025
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A – Alimentary tract and metabolism

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
1	famotidine, calcium carbonate, magnesium hydroxide	Famotidine/calcium carbonate/ magnesium hydroxide 10 mg/800 mg/165 mg	tablets		Rx	Box x 10 tablets	Q4 2025

G – Genito-urinary system and sex hormones

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
G01 – Gynecological antiinfectives and antiseptics							

1	metronidazole, nystatin, neomycin sulfate	Zifex® Trio	pessaries	Tergynan, Lab Bouchara	RX	Box x 10 pessaries	Q4 2025
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M – Musculo-skeletal system

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
M01 – Antiinflammatory and antirheumatic products							

1	naproxen sodium, esomeprazole magnesium	Naproxen/ Esomeprazol 500 mg/20 mg	modified-release tablets	Vimovo, AstraZeneca	OTC	Box x 10 tablets	Q2 2025
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N – Nervous System

N01 – Anesthetics, local							
1	prilocaine, lidocaine hydrochloride	Duocalm® 25 mg/25 mg/ g	cream	EMLA, Astra Zeneca	Rx	Box x 1 tube x 5 g Box x 1 tube x 30 g	EUeCTD Hybrid application Q2 2025

Medical devices (according to Regulation EU 2017/745)

No	Active substance	Brand name	Packaging	File status
1	lactic acid sodium lactate	Zifelle® vaginal pessaries	box x 10 pessaries	DM class IIa, CE mark Q4 2025
2	polysiloxanes, trimethylsiloxysilicate, dimethicone crosopolymer	Siloderm® gel (non-sterile silicone gel for hypertrophic and keloid scars)	box x 1 tube x 15 g	DM Class IIa, available Q4 2025
3	sodium hyaluronate	Zifelle® Hydra vaginal pessaries	box x 10 pessaries	DM class IIa, CE mark Q4 2025
4	sodium hyaluronate lactic acid sodium lactate	Zifelle® Hydra vaginal moisturizer cream	box x 1 tube x 50 g (with applicator)	DM class IIa, CE mark Q4 2025
5	sodium hyaluronate DL-A-Tocopheryl acetate menthol	Hemorsal® antihemorrhoidal suppositories	box x 7 suppositories	DM class IIa, CE mark Q4 2025
6	sodium hyaluronate DL-A-Tocopheryl acetate menthol	Hemorsal® antihemorrhoidal cream	box x 1 tube x 30 g (with applicator)	DM class IIa, CE mark Q4 2025

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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.

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- **Nystatin non-micronized**
- **Nystatin micronized**
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tablets, capsules



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pessaries

- ➔ **Nystatin ATB contains a single polymorphic form, polymorph A respectively.**
- ➔ **This polymorphic form A (dihydrate) is maintained after micronisation, which proves a reproducible process.**
- ➔ **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 to current edition of the EP/ USP Pharmacopeia

- **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
- **RETEST** 36 months

NYSTATIN NON-MICRONIZED

Quality according to 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
- **RETEST** 36 months



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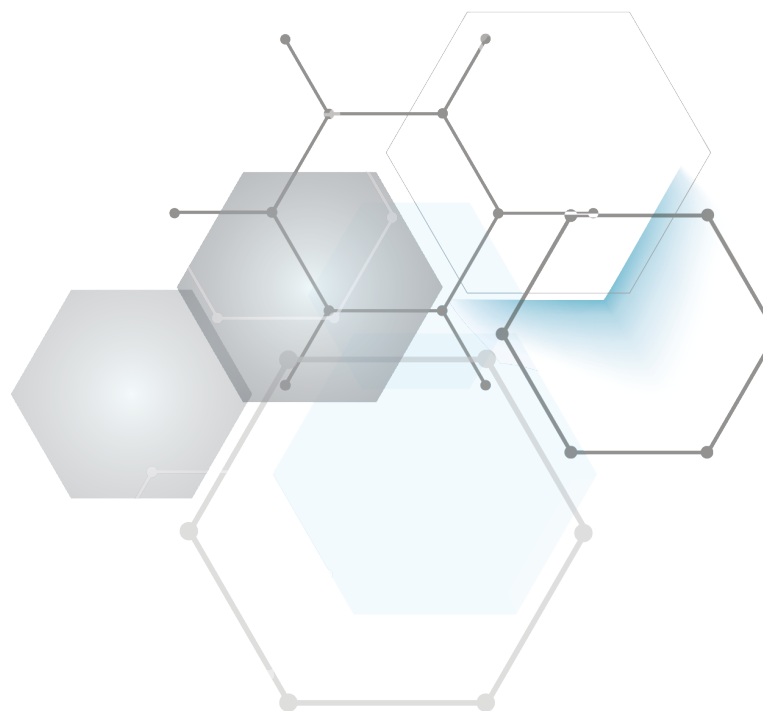
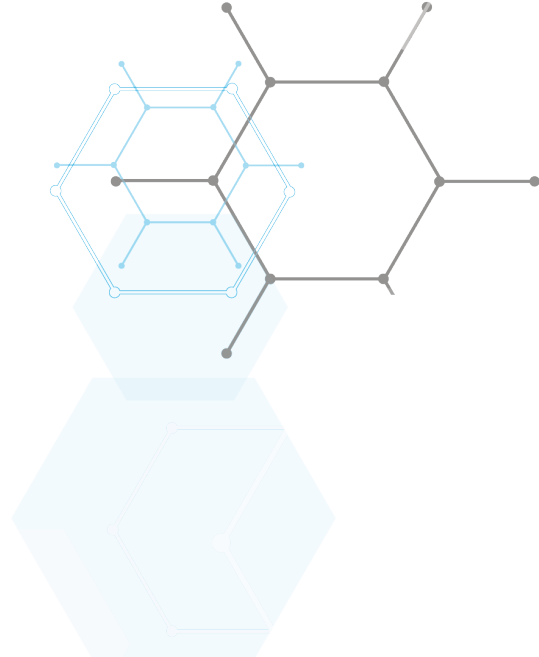
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