



TIEFENBACHER FDF PRODUCT LIST

March 2025

Own development, manufacturing, registration, and supply

TIEFENBACHER PHARMACEUTICALS is pioneering healthcare by making medicines more affordable, more available, and better than before. We offer targeted product solutions that bring added value to patients and ensure our partners a unique position in the market.

Our in-house capacity allows to efficiently develop, manufacture, register, and supply growing patient needs. Thanks to our global regulatory affairs expertise we have already obtained more than 18.000 marketing authorizations in over 80 markets worldwide. Hereby we are always committed to develop with a patient-centered approach – to improve peoples' lives around the world.



Advanced Research and Development

- State-of-the-art R&D and manufacturing site in Hyderabad, India
- Future ready for all types of formulations and different dosage forms (such as tablets, capsules, liquids, and injectables)
- Most modern techniques and software's (e. g. inhouse XRD Crystallography, WinNonlin IVIVC simulation tools, Nitrosamine testing, Malvern particle size testing)



Dedicated Manufacturing Facilities in Europe and India

Fully-fledged manufacturing of solid dosage forms in two dedicated sites:

- Differentiated specialty production Hyderabad, India
- Large-scale production in Cyprus, Europe



Most Modern Technologies

- E.g. hot melt extrusion, nano particles, and spray drying
- New state-of-the-art site for highly potent drugs

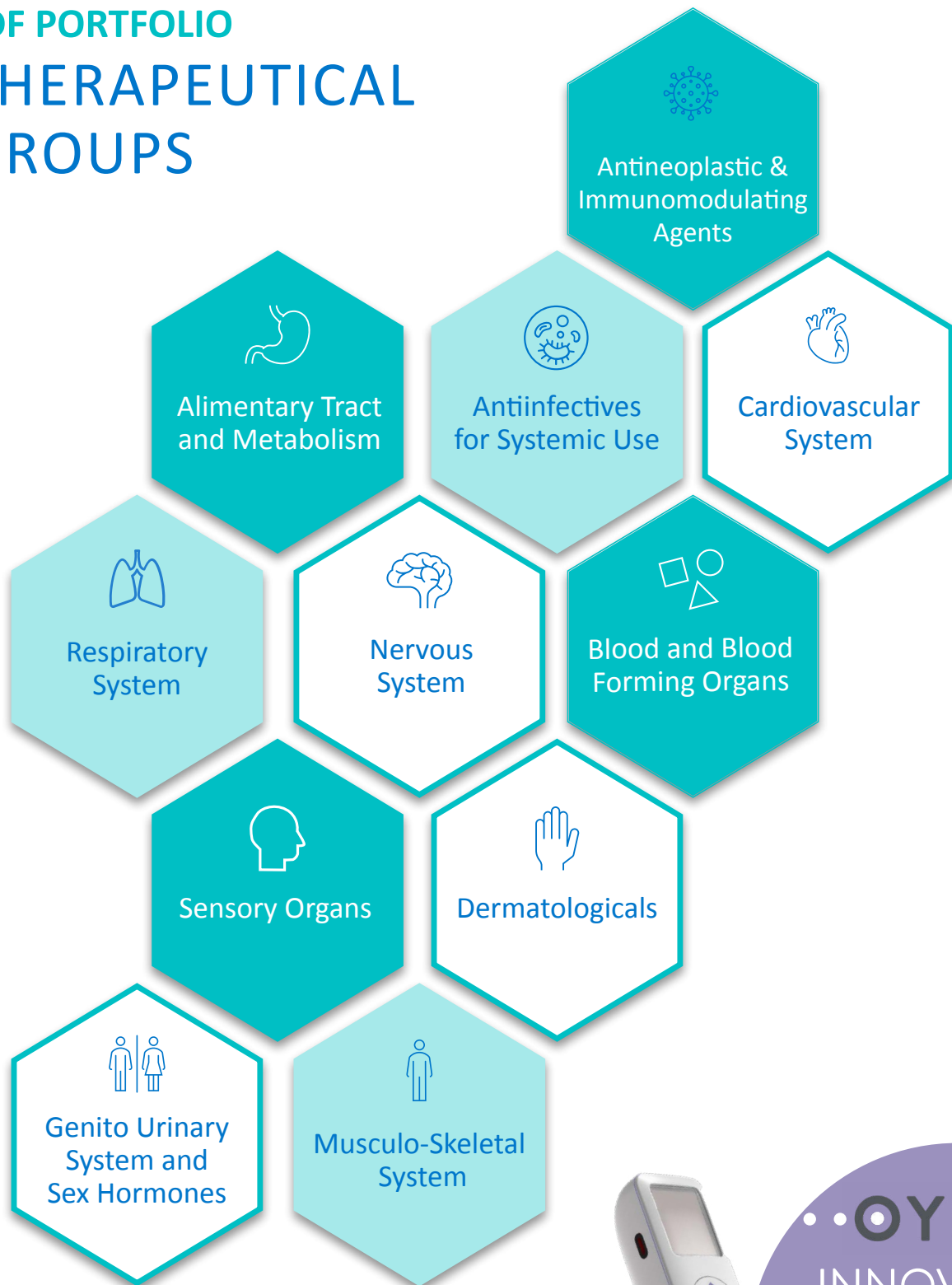


All Important Quality Approvals



And further international approvals.

FDF PORTFOLIO THERAPEUTICAL GROUPS



•• **OYSTA**
INNOVATIVE
HEALTHCARE
SOLUTION
OYSTA®

Please see page 11

Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Alectinib (IN-HOUSE)	Alecensa®	Antineoplastic and Immunomodulating Agents	L01E Protein Kinase Inhibitors	Capsule	150mg* *(Zone IVb)	Q2 2027
Alitretinoin (IN-HOUSE)	Toctino®	Dermatologicals	D11A other dermatological agents for dermatitis excl. corticosteroids	Capsule	10mg 30mg	Q3 2025
Bilastine	Bilaxten®	Respiratory System	R06A Antihistamines for systemic use	Oral Solution	10mg/4ml* *(Zone IVb)	Under development
Darolutamide (IN-HOUSE)	Nubeqa®	Antineoplastic and Immunomodulating Agents	L02B Hormone Antagonists And Related Agents	Film-coated tablet	300mg* *(Zone IVb)	Under development
Levamlodipine (except US)	Conjupri®	Cardiovascular System	C08C Selective calcium channel blockers with mainly vascular effects	Tablet	2,5mg 5mg	Q3 2025
Lithium XR (IN-HOUSE)	Quilonum®	Nervous System	N05AN Psycholeptics bipolar disorders major depression cluster headache	Extended Release tablet	300mg* 450mg* 625mg* *(Zone IVb)	Q1 2027
Macitentan+Tadalafil	Opsynvi®	Cardiovascular System	C02KX54 Other antihypertensives (Pulmonary, Arterial Hypertension)	Tablet	10mg+40mg	Q1 2026
Mercaptamine (IN-HOUSE)	Procsybi®	Alimentary Tract and Metabolism	A16A Other alimentary tract and metabolism products (Cystinosis)	Capsule and stick pack	25mg* cap. 75mg* cap. 75mg* stick packs 300mg* stick packs	Q1 2025
Neratinib (IN-HOUSE)	Nerlynx®	Antineoplastic drugs	L01E Antineoplastic drugs (early-stage hormone receptor positive HER2-overexpressed/ amplified breast cancer)	Film-coated tablet	40mg* 120mg* *(Zone IVb)	Q2 2026
Netupitant+ Palonosetron (IN-HOUSE)	Akynzeo®	Antineoplastic and Immunomodulating Agents	A04AA Serotonin antagonists	Tablet	300mg+0.5mg* *(Zone IVb)	Q3 2025
Niraparib (IN-HOUSE)	Zejula®	Antineoplastic and Immunomodulating Agents	L01X other antineoplastic drugs 2nd line ovarian cancer	Tablet	100mg* 200mg* 300mg* *(Zone IVb)	Under development
Olaparib	Lynparza®	Antineoplastic and Immunomodulating Agents	L01X Cancer Ovarian, Breast, Prostate, Pancreas	Film-coated tablet	100mg* 150mg* *(Zone IVb)	Q2 2025

Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Pitolisant (IN-HOUSE)	Wakix® Ozawade®	Nervous system	N07X treatment of narcolepsy with or without cataplexy	Tablet	4,5mg* 18mg* *(Zone IVb)	Q2 2025
Ponatinib	Iclusig®	Antineoplastic and Immunomodulating Agents	L01E chronic myelogenous leukaemia (CML)	Tablet	15mg 30mg 45mg	Q3 2026
Posaconazol (IN-HOUSE)	Noxafil®	Antiinfectives For Systemic Use	J02A Antimycotics for systemic use (Antifungal)	Gastro-resistant tablet	300mg* *(Zone IVb)	Q2 2025
Regorafenib (IN-HOUSE)	Stivarga®	Antineoplastic and Immunomodulating Agents	L01E Protein kinase inhibitor colorectal cancer gastrointestinal stromal tumors hepatocellular carcinoma	Tablet	40mg* 160mg* *(Zone IVb)	Q1 2027
Trientine (IN-HOUSE)	Cuprior™	Alimentary Tract and Metabolism	A16A Other Alimentary Tract And Metabolism Products	Film-coated tablet	75mg* 150mg* *(Zone IVb)	Q4 2025
Vismodegib (IN-HOUSE)	Erivedge®	Antineoplastic and Immunomodulating Agents	L01XJ01 Hedgehog pathway inhibitors	Capsule	150mg* *(Zone IVb)	Q4 2025
Venetoclax (IN-HOUSE)	Venclexta®/ Venclyxto®	Antineoplastic and Immunomodulating Agents	L01X Other antineoplastic agents (Chronic lymphocytic leukaemia (CLL), acute myeloid leukaemia (AML))	Film-coated tablet	10mg 50mg 100mg* *(Zone IVb)	Q2 2027

Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Apremilast (IN-HOUSE)	Otezla®	Antineoplastic and Immunomodulating Agents	L04A Immunosuppressants (Psoriasis and psoriatic arthritis)	Film-coated tablet	10mg 20mg 30mg	Under Registration
Butylscopolamin+ Paracetamol (IN-HOUSE)	Buscopan PLUS®	Alimentary Tract and Metabolism	A03B Belladonna and derivatives, plain (Spasmolytic)	Film-coated tablet	10mg+500mg*	Under Registration
Edoxaban (IN-HOUSE)	Lixiana®	Blood and Blood Forming Organs	B01A Antithrombotic agents (Stroke)	Film-coated tablet	15mg* 30mg* 60mg* *(Zone IVb)	Under Registration
Ibuprofen+ Caffeine	Thomapyrin Tension Duo®	Musculo-Skeletal System	M01A Antiinflammatory And Antirheumatic Products, Non-Steroids	Sachet		Under Registration
Macitentan US	Opsumit®	Cardiovascular System	C02K Other antihypertensives (Pulmonary, Arterial Hypertension)	Film-coated tablet	10mg* *(Zone IVb)	Under Registration
Minoxidil	Lonolox®	Cardiovascular System	C02DC01 Therapy resistant hypertension	Tablet	2,5 mg 5 mg 10 mg	Under Registration
Nalmefene	Selincro®	Nervous System	N07B Alcohol-Related Disorders	Film-coated tablet	18mg* *(Zone IVb)	Under Registration
Rivaroxaban+ Acetylic Acid (IN-HOUSE)		Blood and Blood Forming Organs	B01A Antithrombotic agents (Coronary Syndroms, Coronary Artery Disease, Symtomatic Peripheral Arterial Disease)	Film-coated tablet Combi blister	2,5mg+100mg* *(Zone IVb)	Under Registration
Sacubitril+ Valsartan EU (IN-HOUSE)	Entresto®	Cardiovascular System	C09D Angiotensin II receptor blockers (ARBs), plain (Chronic Heart Failure)	Film-coated tablet	24mg+26mg* 49mg+51mg* 97mg+103mg* *(Zone IVb)	Under Registration

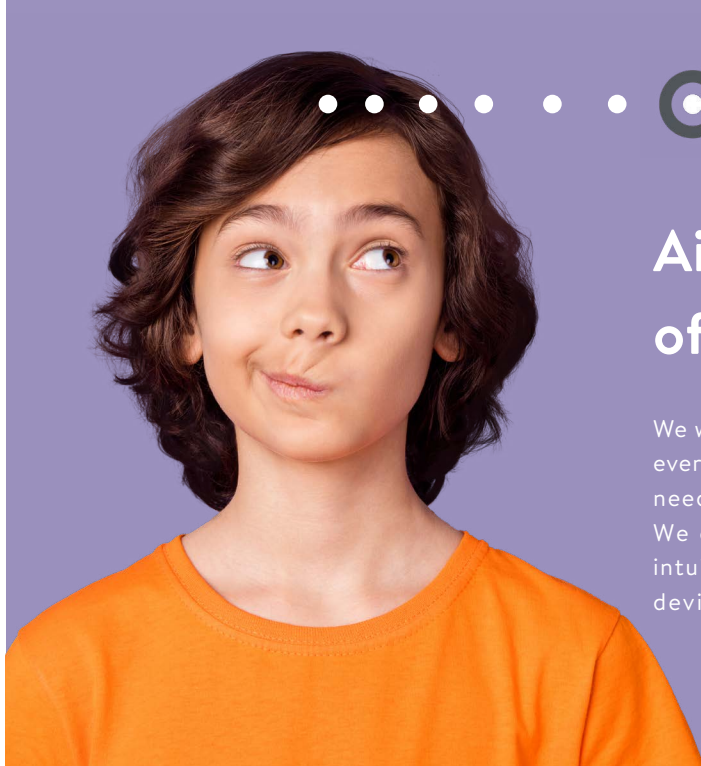
Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Abiraterone	Zytiga®	Antineoplastic and Immunomodulating Agents	L02B Hormone antagonists and related agents (Prostatic Neoplasms)	Tablet, Film-coated tablet	250mg* 500mg* *(Zone IVb)	Registered in EU
Abiraterone + Prednisolone	Abiraterone:Zytiga® Prednisolone:Pfizer®	Antineoplastic and Immunomodulating Agents	L02B Hormone antagonists and related agents (Prostatic Neoplasms)	Film-coated tablet	500mg+5mg 500mg+10mg	Registered in EU
Ambrisentan (IN-HOUSE)	Volibris®	Cardiovascular System	C02K Other antihypertensives (Pulmonary, Arterial Hypertension)	Film-coated tablet	5mg* 10mg* *(Zone IVb)	Registered in EU
Amifampridine (IN-HOUSE)	Firdapse®	Nervous System	N07X Other nervous system drugs (Lambert-Eaton Myasthenic Syndrome)	Tablet	10mg	Registered in EU
Apixaban	Eliquis®	Blood and Blood Forming Organs	B01A Antithrombotic agents (Stroke, Heart Attack)	Tablet	2.5mg, 5mg	Registered in EU
Arsenic trioxide	Trisenox®	Antineoplastic and Immunomodulating Agents	L01XX27 Induction of remission and consolidation in patients with acute promyelocytic leukemia (APL)	vial	1 mg/ml	Registered in EU
Atorvastatin+ Ezetimibe	Atozet®	Cardiovascular System	C10B Lipid modifying agents, combinations (Hyperlipidemia)	Film-coated tablet	10mg+10mg 20mg+10mg 40mg+10mg 80mg+10mg	Registered in EU
Bilastine	Bilaxten®	Respiratory System	R06A Antihistamines for systemic use	Tablet	20mg* *(Zone IVb)	Registered in EU
Bilastine ODT	Bilaxten®	Respiratory System	R06A Antihistamines for systemic use	Orodispersible tablet	10mg 20mg* *(Zone IVb)	Registered in EU
Bimatoprost	Lumigan®	Sensory Organs	S01E Antiglaucoma	Solution	0.1mg/ml 0.3mg/ml	Registered in EU
Bimatoprost+ Timolol	Ganfort®	Sensory Organs	S01E Antiglaucoma	Solution	0.3mg/ml+5mg/ml	Registered in EU
Brimonidine	Alphagan®	Sensory Organs	S01G Decongestants and antiallergics	Solution	2mg/ml	Registered in EU
Brimonidine+ Timolol	Combigan®	Sensory Organs	S01G Decongestants and antiallergics	Solution	2mg+5mg/ml*	Registered in EU
Brivudine (IN-HOUSE)	Zostex®	Anti-infective for Systemic Use	J05A Antiviral (Herpes Zoster)	Tablet	125mg* *(Zone IVb)	Registered in EU
Buprenorphine	Transtec PRO®	Nervous System	N02A Opioids (Analgesic Malignant Pain)	Transdermal patch	35µg/h* 52.5µg/h 70µg/h* (4-day patch) *(Zone IVb)	Registered in EU

Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Buprenorphine	Norspan®	Nervous System	N02A Opioids (Analgesic Non-Malignant Pain)	Transdermal patch	5µg/h 10µg/h 15µg/h 20µg/h (7-day patch)	Registered in EU
Carvedilol (IN-HOUSE)	Dilatrend®	Cardiovascular System	C07A Beta blocking agents (Hypertension)	Film-coated tablet	3.125mg 6.25mg 12.5mg 25mg	Registered in EU
Escitalopram (IN-HOUSE)	Cipralext®	Nervous System	N06A Antidepressants (Depression)	Film-coated tablet	5mg 10mg 15mg 20mg* *(Zone IVb)	Registered in EU
Eslicarbazepin (IN-HOUSE)	Exalief®/ Zebinix®	Nervous System	N03A Antiepileptics (Epilepsy)	Tablet	200mg* 400mg* 600mg* 800mg* *(Zone IVb)	Registered in EU
Eszopiclone	Lunesta®/ Eszop®	Nervous System	N05C Hypnotics and sedatives (Insomnia)	Film-coated tablet	1mg 2mg 3mg	Registered in EU
Etoricoxib (IN-HOUSE)	Arcoxia®	Musculo-Skeletal System	M01A Antirheumatic	Film-coated tablet	30mg* 60mg* 90mg* 120mg* *(Zone IVb)	Registered in EU
Fingolimod	Gilenya®	Antineoplastic and Immunomodulating Agents	L04A Immunosuppressants (Multiple Sclerosis)	Capsule	0.5mg* *(Zone IVb)	Registered in EU
Gabapentin	Neurontin®	Nervous System	N03A Antiepileptics (Epilepsy)	Capsule	100mg 300mg 400mg	Registered in EU
Gabapentin	Neurontin®	Nervous System	N03A Antiepileptics (Epilepsy)	Film-coated tablet	600mg 800mg	Registered in EU
Ivabradine (IN-HOUSE)	Procoralan®	Cardiovascular System	C01E Other cardiac preparations (Angina pectoris)	Film-coated tablet	5mg* 7.5mg* *(Zone IVb)	Registered in EU
Lacosamide	Vimpat®	Nervous System	N03A Antiepileptics (Epilepsy)	Film-coated tablet	50mg* 100mg* 150mg* 200mg* *(Zone IVb)	Registered in EU
Lamotrigine	Lamictal®	Nervous System	N03A Antiepileptics (Epilepsy, Depression)	Tablet	25mg 50mg 100mg 200mg	Registered in EU
Latanoprost	Xalatan®	Sensory Organs	S01E Antiglaucoma	Solution	50µg/ml	Registered in EU
Latanoprost+ Timolol	Xalacom®	Sensory Organs	S01E Antiglaucoma	Solution	50µg/ml+5mg/ml	Registered in EU
Leflunomide	Arava®	Antineoplastic and Immunomodulating Agents	L04A Immunosuppressants (Rheumatoid arthritis and psoriatic arthritis)	Film-coated tablet	10mg 20mg* *(Zone IVb)	Registered in EU+US

Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Leflunomide	Arava®	Antineoplastic and Immunomodulating Agents	L04A Immunosuppressants (Rheumatoid arthritis and psoriatic arthritis)	Film-coated tablet	15mg* *(Zone IVb)	Registered in EU
Montelukast	Singulair®	Respiratory System	R03D Other systemic drugs for obstructive airway diseases	Chewable tablet	4mg 5mg	Registered in EU
Montelukast	Singulair®	Respiratory System	R03D Other systemic drugs for obstructive airway diseases	Film-coated tablet	10mg* *(Zone IVb)	Registered in EU
Pantoprazole (IN-HOUSE)	Pantozol®	Alimentary Tract and Metabolism	A02B Drugs for peptic ulcer and gastro-oesophageal reflux disease (Proton Pump Inhibitor)	Enteric-coated tablet	20mg* 40mg* *(Zone IVb)	Registered in EU
Pirfenidone	Intermune®	Antineoplastic and Immunomodulating Agents	L04AX05 Antineoplastic and immunomodulating agent	Film-coated tablet	267mg 534mg 801mg	Registered in EU+US
Posaconazol (IN-HOUSE)	Noxafil®	Anti-infective for Systemic Use	J02A Antimycotics for systemic use (Antifungal)	Gastro-resistant tablet	100mg* *(Zone IVb)	Registered in EU
Pravastatin	Pravasin®	Cardiovascular System	C10A Lipid modifying agents, plain (Cholesterol-Lowering)	Film-coated tablet	10mg 20mg 40mg	Registered in EU
Prucaloprid (IN-HOUSE)	Resolor®	Alimentary Tract and Metabolism	A06A Drugs for constipation	Film-coated tablet	1mg* 2mg* *(Zone IVb)	Registered in EU
Quetiapine	Seroquel®	Nervous System	N05A Antipsychotics	Film-coated tablet	25mg* 100mg* 150mg 200mg* 300mg* *(Zone IVb)	Registered in EU
Quinine Sulfate (IN-HOUSE)	Limptar®	Musculo-skeletal system	P01BC01, M09AA72 Muscle relaxant, antimalarial agent	Film-coated tablet	200mg	Registered in EU
Rasagiline (IN-HOUSE)	Azilect®	Nervous System	N04B Dopaminergic agents (Parkinson)	Tablet	1mg* *(Zone IVb)	Registered in EU
Rivaroxaban (IN-HOUSE)	Xarelto®	Blood and Blood Forming Organs	B01A Antithrombotic agents (Stroke, Heart Attack)	Film-coated tablet	2.5mg 10mg* 15mg* 20mg* *(Zone IVb)	Registered in EU
Teriflunomide (IN-HOUSE)	Aubagio®	Antineoplastic and Immunomodulating Agents	L04A Immunosuppressants (Multiple Sclerosis)	Film-coated tablet	7mg 14mg* *(Zone IVb)	Registered in EU+US
Ticagrelor (IN-HOUSE)	Brilique®	Blood and Blood Forming Organs	B01A Antithrombotic agents (Stroke, Heart Attack)	Film-coated tablet	60mg* 90mg* *(Zone IVb)	Available for Technical Transfer

Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Varenicline Citrate (IN-HOUSE)	Champix®	Nervous System	N07B Drugs used in addictive disorders (Nicotine Dependents)	Film-coated tablet	0.5mg* 1mg* *(Zone IVb)	Registered in EU
Vildagliptin	Galvus®	Alimentary Tract and Metabolism	A10B Blood glucose lowering drugs, excluding insulins (Diabetes Mellitus)	Tablet	50mg* *(Zone IVb)	Registered in EU
Vildagliptin+ Metformin	Eucreas®	Alimentary Tract and Metabolism	A10B Blood glucose lowering drugs, excluding insulins (Diabetes Mellitus)	Film-coated tablet		Registered in EU

TIEFENBACHER GROUP AND ONDOSIS LAUNCH THE INNOVATIVE HEALTHCARE SOLUTION OYSTA®



OYSTA

Aiming to improve the lives of people with ADHD

We want to revolutionize how patients take their medicines so that every individual gets precisely the right dose of the medicine they need in a simpler, more comfortable way.

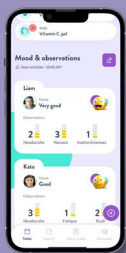
We combine pharmaceuticals and technology to guarantee intuitive, precise, and flexible dosing via a connected handheld device (under development) and follow up in digital solution.

OYSTA – how it works

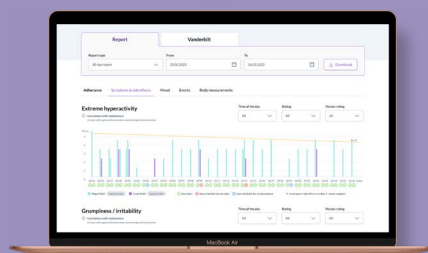
Flexible Dosing of Oral Solids

Dosing Control

Connected Care



Mobile app for patients to support therapy management and promote adherence



Web portal for healthcare providers to monitor therapy and communicate with patients



Dosage manager for flexible and precise dosing of medication and dosing control

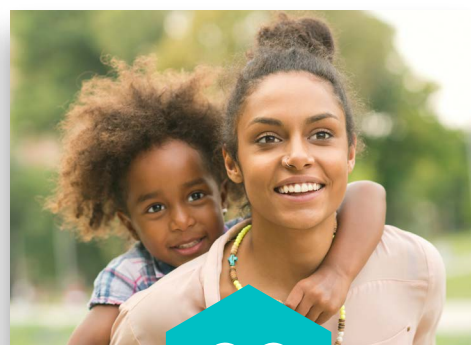
For more information about OYSTA please contact us via info@oysta-health.com and visit our web page on www.oysta-health.com



BETTER
AFFORDABILITY



BETTER GLOBAL
AVAILABILITY



BETTER
THERAPY

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