



# TIEFENBACHER FDF PRODUCT LIST

May 2024

## 1. TIEFENBACHER LABORATORIES

### OUR ADVANCED, FDA APPROVED MANUFACTURING SITE IN INDIA



TIEFENBACHER LABORATORIES is a state-of-the-art manufacturing site, located in Hyderabad, India. Featuring a GMP-compliant environment, TIEFENBACHER LABORATORIES is equipped with the most modern technologies for manufacturing, testing, packing, warehousing, and releasing of solid oral dosage forms. The facility has a strong track record in developing and manufacturing with special technologies to increase the bioavailability of APIs, such as hot-melt-extrusion, nano particles, and spray drying. Moreover, the site has currently expanded its capabilities to develop and manufacture finished dosage forms with high potent molecules. TIEFENBACHER LABORATORIES holds the ISO 14001:2014 and ISO 18001:2015 certifications and has been successfully inspected by the German, Turkish, UAE, and Saudi authorities as well as the U.S.FDA.

**> 35% IN-HOUSE PRODUCTION**

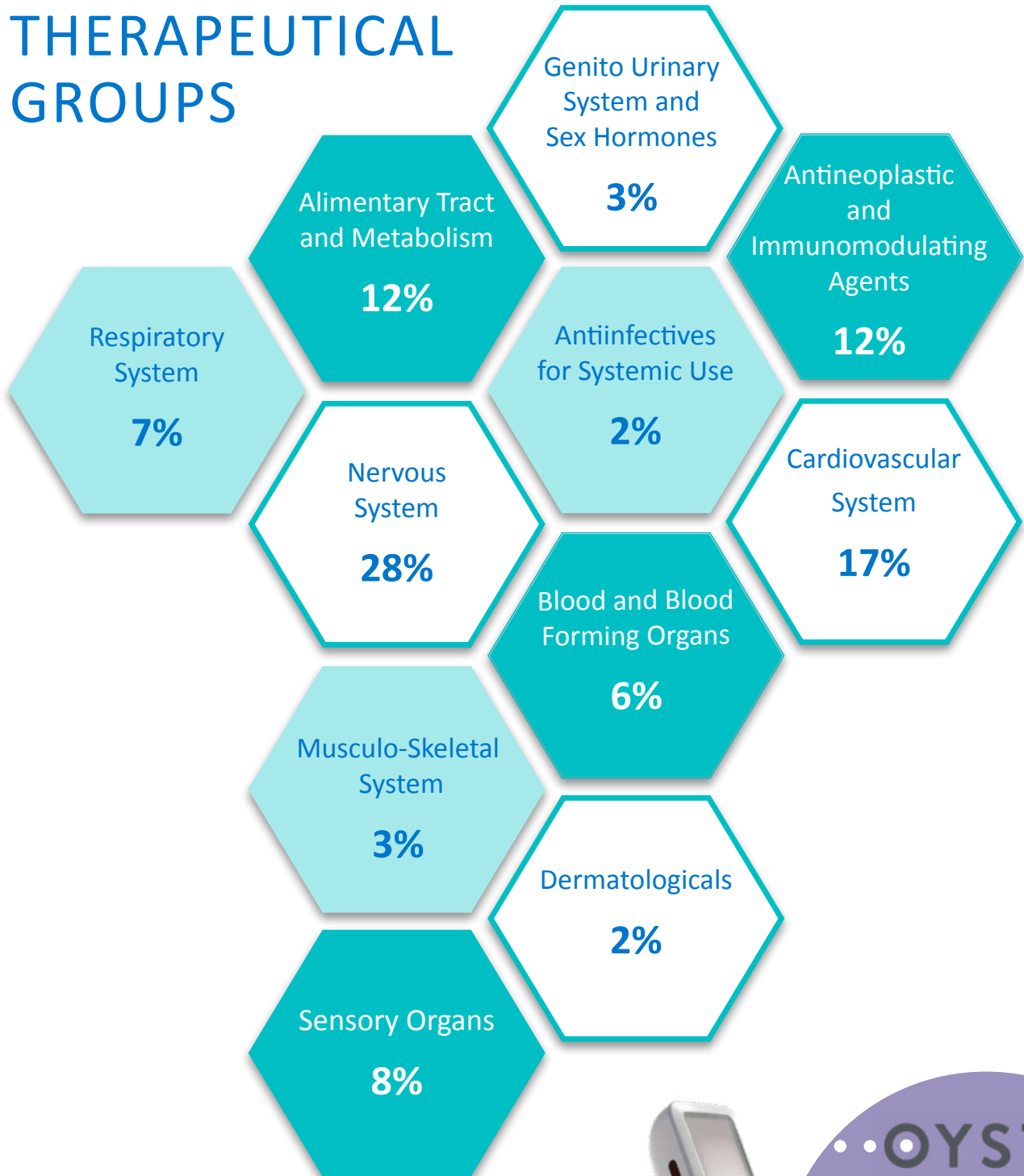


## 2. Delorbis Pharmaceuticals

### HIGH VOLUME PRODUCTIONS MADE IN EUROPEAN UNION

The manufacturing facilities of TIEFENBACHER GROUP on Cyprus have been designed to accommodate bulk production and primary and secondary packaging operations of non-sterile oral solid dosage forms (tablets, capsules, and powder suspensions for reconstitution). Thanks to the state-of-the-art equipment, Delorbis offers a broad service package including testing, releasing, and warehousing. The production and packaging lines are equipped with the most economic and sophisticated technologies from the first manufacturing step to the last packaging step and have the flexibility to manage small batch sizes as well as high volume productions. The facility has recently extended its production capacity, equipment, and warehouse storage to drive efficiency and to meet the growing demand of our customers.

## FDF PORTFOLIO THERAPEUTICAL GROUPS



•• OYSTA  
INNOVATIVE  
HEALTHCARE  
SOLUTION  
OYSTA®

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Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Enzalutamide (IN-HOUSE)	Xtandi®	Antineoplastic and Immunomodulating Agents	L02B Hormones and related agents (Prostate Cancer)	Film-coated tablet	40mg* 80mg* 120mg* 160mg* *(Zone IVb)	Under Development
Macitentan	Opsumit®	Cardiovascular System	C02K Other antihypertensives (Pulmonary, Arterial Hypertension)	Film-coated tablet	10mg* *(Zone IVb)	Q2 2024
Olaparib	Lynparza®	Antineoplastic and Immunomodulating Agents	L01X Cancer Ovarian, Breast, Prostate, Pancreas	Film-coated tablet	100mg* 150mg* *(Zone IVb)	Under Development
Palbociclib (IN-HOUSE)	Ibrance®	Antineoplastic and Immunomodulating Agents	L01EF Cyclin-dependent kinase (CDK) inhibitors	film-coated tablet	75mg* 100mg* 125mg* *(Zone IVb)	Under Development
Piribedil (IN-HOUSE)	Clarium®	Nervous system	N04B Parkinson disease	Retard Tablet	50mg* *(Zone IVb)	Q2 2025
Pitolisant (IN-HOUSE)	Wakix® Ozawade®	Nervous system	N07X treatment of narcolepsy with or without cataplexy	Tablet	4,5mg* 18mg* *(Zone IVb)	Q3 2024
Regorafenib (IN-HOUSE)	Stivarga®	Antineoplastic and Immunomodulating Agents	L01E Protein kinase inhibitor colorectal cancer gastrointestinal stromal tumors hepatocellular carcinoma	Tablet	40mg	Under Development
Rifaximin (IN-HOUSE)	Normix®	Alimentary Tract and Metabolism	A07A Intestinal anti-infectives (200mg: Travellers Diarrhea; 550mg: Hep. Encephalopathy)	Film-coated tablet	200mg 550mg	Under Development
Safinamide (IN-HOUSE)	Xadago®	Nervous system	N04B Parkinson disease	Film-coated tablet	50mg* 100mg*	Q3 2024
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)	Under Development

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
Edoxaban (IN-HOUSE)	Lixiana®	Blood and Blood Forming Organs	B01A Antithrombotic agents (Stroke)	Film-coated tablet	15mg* 30mg* 60mg* *(Zone IVb)	Under Registration
Macitentan US	Opsumit®	Cardiovascular System	C02K Other antihypertensives (Pulmonary, Arterial Hypertension)	Film-coated tablet	10mg* *(Zone IVb)	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
Varenicline Citrate (IN-HOUSE)	Champix®	Nervous System	N07B Drugs used in addictive disorders (Nicotine Dependents)	Film-coated tablet	0.5mg* 1mg* *(Zone IVb)	Under Registration
Varenicline Tartrate (IN-HOUSE)	Champix®	Nervous System	N07B Drugs used in addictive disorders (Nicotine Dependents)	Film-coated tablet	0.5mg* 1mg* *(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
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	Zostex®	Anti infective Agent	J05A Antiviral (Herpes Zoster)	Tablet	125mg	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
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

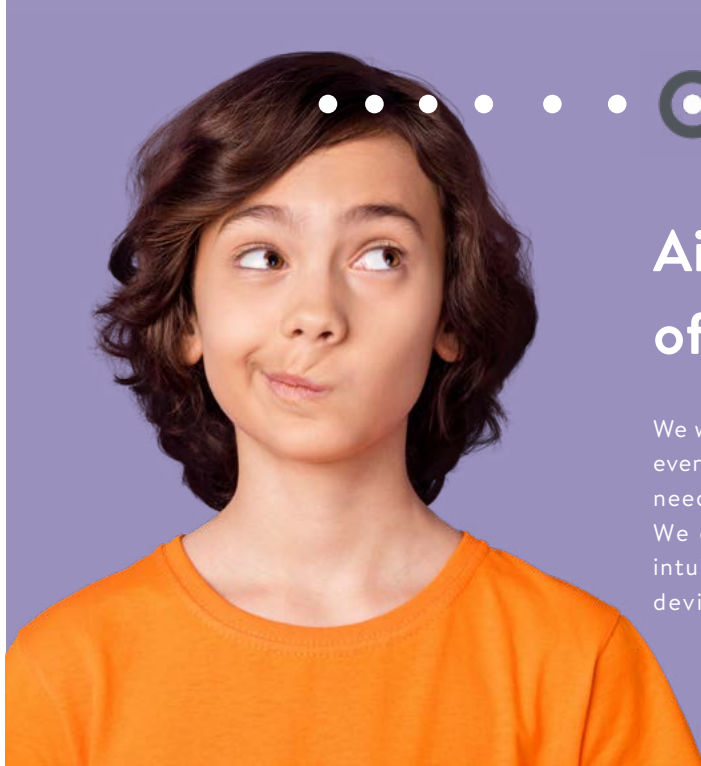
Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Dasatinib	Sprycel®	Antineoplastic and Immunomodulating Agents	L01X Protein kinase inhibitors (CML/ALL)	Film-coated tablet	20mg 50mg 70mg 80mg 100mg 140mg	Registered in EU
Desloratadine	Aerius®/ Clarinet®	Respiratory System	R06A Antihistamines for systemic use	Film-coated tablet	5mg* *(Zone IVb)	Registered in EU
Escitalopram (IN-HOUSE)	Ciprallex®	Nervous System	N06A Antidepressants	Film-coated tablet	5mg 10mg 15mg 20mg* *(Zone IVb)	Registered in EU
Eslicarbazepin	Exalief®/ Zebinix®	Nervous System	N03A Antiepileptics (Epilepsy)	Tablet	200mg* 400mg* 600mg* 800mg* *(Zone IVb)	Registered in EU
Eszopiclone (IN-HOUSE)	Lunesta®/ Ezop®	Nervous System	N05C Hypnotics and sedatives	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
Finasteride	Proscar®	Genito Urinary System and Sex Hormones	G04C Drugs used in benign prostatic hypertrophy (BPH)	Film-coated tablet	5mg	Registered in EU
Finasteride	Propecia®	Dermatologicals	D11A Other dermatological preparations (Alopecia)	Film-coated tablet	1mg	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

Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
Lamotrigine	Lamictal®	Nervous System	N03A Antiepileptics (Epilepsy, Depression)	Orodispersible tablet	5mg 25mg 50mg* 100mg* 200mg *(Zone IVb)	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 Immu- nomodulating Agents	L04A Immunosuppressants (Rheumatoid arthritis and psoriatic arthritis)	Film-coated tablet	10mg 20mg* *(Zone IVb)	Registered in EU
Leflunomide US	Arava®	Antineoplastic and Immu- nomodulating Agents	L04A Immunosuppressants (Rheumatoid arthritis and psoriatic arthritis)	Film-coated tablet	10mg 20mg* *(Zone IVb)	Registered in US
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 In- hibitor)	Enteric-coated tablet	20mg* 40mg* *(Zone IVb)	Registered in EU
Pirfenidone	Intermune®	immunosuppressant	L04AX05 Antineoplastic and im- munomodulating agent	Film-coated tablet	267mg 534mg 801mg	Registered in EU
Posaconazol (IN-HOUSE)	Noxafil®	Antiinfectives For Syste- mic Use	J02A Antimycotics for syste- mic use (Antifungal)	Gastro-resistant tablet	100mg* *(Zone IVb)	Registered in EU
Pravastatin	Pravasin®	Cardiovascular System	C10A Lipid modifying agents, plain (Cholesterol-Lowe- ring)	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



Product	Brand (RLD)	Therapeutical Group	ATC-Indication	Pharmaceutical Form	Strength	Dossier Status
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
Temozolomide	Temodal®	Antineoplastic and Immu- nomodulating Agents	L01A Alkylating agents (Brain Tumors)	Capsule	5mg 20mg 100mg* 140mg 180mg 250mg *(Zone IVb)	Registered in EU
Teriflunomide (IN-HOUSE)	Aubagio®	Antineoplastic and Immu- nomodulating Agents	L04A Immunosuppressants (Multiple Sclerosis)	Film-coated tablet	7mg 14mg* *(Zone IVb)	Registered in EU
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 Trans- fer
Vildagliptin	Galvus®	Alimentary Tract and Metabolism	A10B Blood glucose lowe- ring drugs, excluding insulins (Diabetes Mellitus)	Tablet	50mg* *(Zone IVb)	Registered in EU
Vildagliptin+ Metformin	Eucreas®	Alimentary Tract and Metabolism	A10B Blood glucose lowe- ring drugs, excluding insulins (Diabetes Mellitus)	Film-coated tablet		Registered in EU

# TIEFENBACHER GROUP AND ONDOSIS LAUNCH THE INNOVATIVE HEALTHCARE SOLUTION OYSTA®



## • • • • • OYSTA

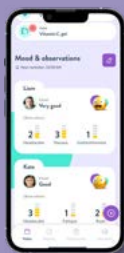
### Aiming to improve the lives of people with ADHD

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.

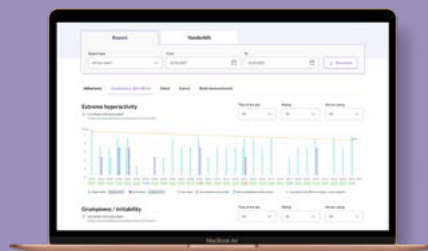
### OYSTA – how it works

• • • Flexible Dosing of Oral Solids •



Mobile app for patients to support therapy management and promote adherence

• Dosing Control •



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

• Connected Care •



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

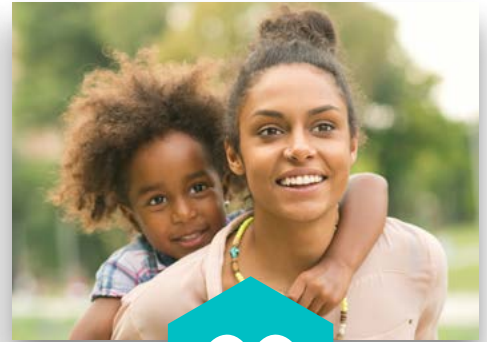
For more information about OYSTA please contact us via [info@oysta-health.com](mailto:info@oysta-health.com) and visit our web page on [www.oysta-health.com](http://www.oysta-health.com)



BETTER  
AFFORDABILITY



BETTER GLOBAL  
AVAILABILITY



BETTER  
THERAPY

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