



KERN
P H A R M A

INTERNATIONAL PRODUCT LIST 2023



“ “ To improve people’s health and quality of life by contributing to the sustainability of the social care system ” ”



**KERN PHARMA'S
EVOLUTION**



**TYPE OF BUSINESS /
BUSINESS TURN OVER**



**PHARMACEUTICAL
DOSAGE FORMS**



**PRODUCT
CLASSIFICATION**



**LATE STAGE
DEVELOPMENT**



**AVAILABLE
PRODUCTS**



**QUALITY
COMMITMENT**



A SUCCESSFUL HISTORY



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PHARMACEUTICAL DOSAGE FORMS



PRODUCT CLASSIFICATION



LATE STAGE DEVELOPEMENT PRODUCTS



AVAILABLE PRODUCTS



QUALITY COMMITMENT

1999

Indukern Group acquires the manufacturing site from Roche

2001

Kern Pharma develops and launches it's first generic Clarithromycin

2003

Signed a Contract Manufacturing agreement with Bayer for a world wide production creams and ointments

2007

New liquids creams production plant ready to operate

2009

X Aniversary
580 employees
92 products
81 Mill. units produced
127. Mill. € turnover

2011

Kern Pharma launches OTC line Personal Care

2012

Kern Pharma reaches a production above 100mio. units per year

2014

New automated warehouse. Adquisition of women's health Division (Gynea)

2015

Creation of biosimilar unit: Kern Pharma Biologics

2016

Kern Pharma acquires 60% of Granard in the USA and sets up it's subsidiary in this country

2017

Kern Pharma acquires Actafarma, which specializes in self-care products

2018

Calier celebrates it's 50th anniversary

2019

Kern Pharma celebrates it's 20th anniversary

2021

Grupo Indukern sells Indukern to the Belgian multinational Ravago Group

2022

We start building a new production plant for injectables in Monforte de Lemos (Galicia)



TYPE OF BUSINESS



DISTRIBUTION AGREEMENTS



LICENSE AND SUPPLY AGREEMENTS



CONTRACT MANUFACTURING



API'S NARCOTICS AND VETERINARY



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AVAILABLE PRODUCTS

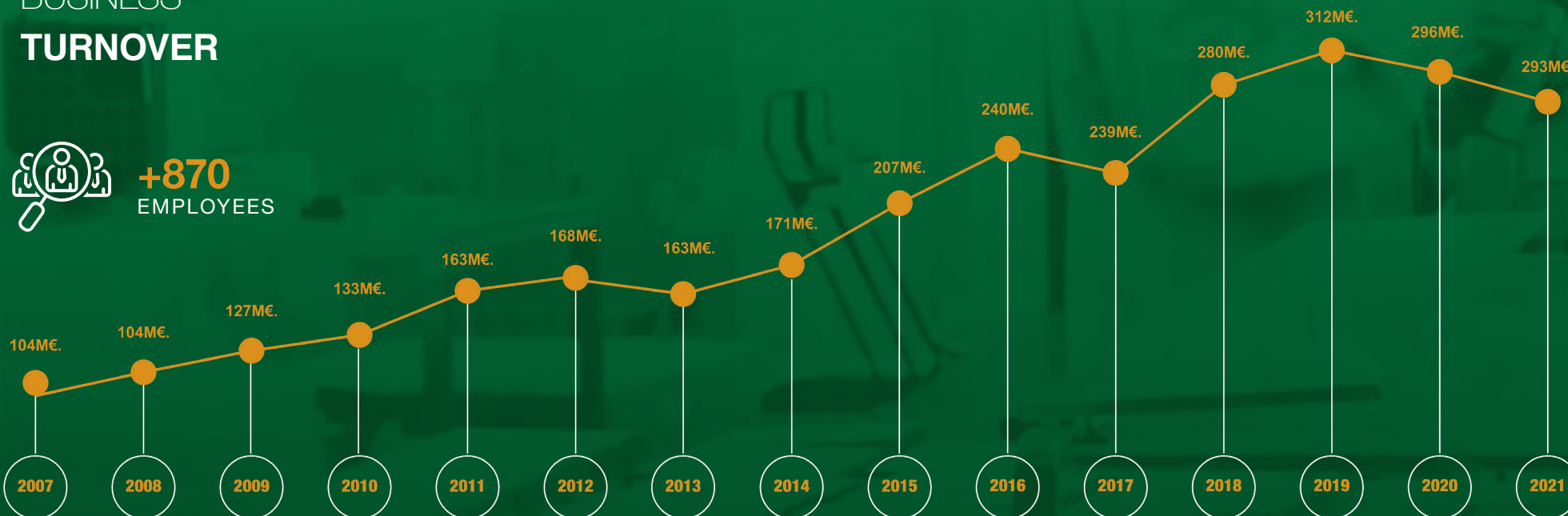


QUALITY COMMITMENT

BUSINESS TURNOVER



+870
EMPLOYEES





PHARMACEUTICAL DOSAGE FORMS



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QUALITY
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1,500 MILLIONS

TABLETS AND CAPSULES



35,2 MILLIONS

STICK-PACKS



28,5 MILLIONS

GRANULE SACHETS



32 MILLIONS

AMPOULES AND VIALS



14,8 MILLIONS

TUBES OF CREAMS AND OINTMENTS



2,1 MILLIONS

SOLUTIONS AND SYRUPS



260 mil.

VAGINAL RINGS



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QUALITY
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Analgesics



Cardiovascular



Oral Antidiabetics



Antifungals



C.N.S.



Oncology



Antihistaminics



Contraceptives



Respiratory System



Antiinfectives



Gastrointestinal



Urology



Antiinflammatories



Musculoskeletal



Venous System



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Cardiovascular

PRODUCT	STRENGTH	PHARMACEUTICAL FORM	DATE OF DOSSIER DEVELOPMENT	TYPE OF APPLICATION	INNOVATOR BRAND
Apixaban	2,5 mg 5 mg	Tablets	2023	Generic	Eliquis® (Bristol-Myers)
Edoxaban <i>(New)</i>	15 mg 30 mg 60 mg	Film-coated tablets	2023	Generic	Lixiana® (Daiichi Sankyo Europe GmbH)



Musculoskeletal

Ibuprofen Arginine	400 mg	Film-coated tablets	2024	Generic	Espidifen® (Zambon)
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Oral Antidiabetics

Linagliptin	5 mg	Tablets	2024	Generic	Trajenta® (Boehringer Ingelheim International GmbH)
Empagliflozin <i>(New)</i>	10mg 25mg	Tablets	2024	Generic	Jardiance® (Boehringer Ingelheim International GmbH)



Venous System

Diosmin/Hesperidin (Flavonoid Fraction)	1.000 mg /10 ml	Oral suspension (Stick Pack)	2023	Well established use	Daflon® (Servier)
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INNOVATOR BRAND



Respiratory System

Cloperastine

3.54 mg/ml

Oral suspension (Stick Pack)

2023

Generic

Flutox® (Zambon)

Acetylcysteine *(New)*

100 mg/ml

Solution for injection (Ampoule)

2023

Generic

Flumil® (Zambon)



Antihistaminics

Desloratadine

5 mg

Oral Suspension (Stick Pack)

2023

Well established use

N/A



C.N.S.

Diazepam *(New)*

10 mg/2ml

Solution for injection (Ampoule)

2023

Generic

Valium® (Atrahs Pharma Netherlands B.V.)



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Analgesics

PRODUCT	STRENGTH	PHARMACEUTICAL FORM	DATE OF DOSSIER DEVELOPMENT	TYPE OF APPLICATION	INNOVATOR BRAND
Fentanyl Injectable	0,05 mg/ml	Solution for injection (Ampoule)	2010	Well established use	N/A
Fentanyl	100 mcg 200 mcg 300 mcg 400 mcg 600 mcg 800 mcg	Sublingual tablets	2017	Generic	Abstral® (Prostakan)
Paracetamol	500 mg 650 mg 1 g	Oral solution (Stick Pack)	2014	Well established use	N/A
	500 mg 650 mg 1 g	Tablets	2005		
Tramadol/Paracetamol	37,5 mg/325 mg 75 mg/650 mg	Tablets Film-coated tablets	2010 2021	Generic	Zaldiar® (Grünenthal)



Antifungals

Ketoconazole	20 mg/g	Cream	2017	Hybrid	Ketoisdin® (Isdin)
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Antiinfectives

Clarithromycin	250 mg 500 mg	Film-coated tablets	2001	Hybrid	Klacid® (Abbot)
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Antiinflammatories

Dexamethasone	4 mg/ml	Solution for injection Ampoules of: 1 ml 1.8 (Format Covid) 5 ml	2019	Generic	Fortecortin® (Merck)
Diclofenac	11.6 mg/g 23.2 mg/g	Gel	2008 2021	Hybrid	Voltadol® (GSK) Voltadol Forte® (GSK)
Ibuprofen	20 mg/ml	Oral suspension	2014	Well Established Use	Dalsy® (Mylan)
	40 mg/ml	Oral suspension	2014	Well Established Use	Neobrufen® (Abbot)
	200 mg 400 mg 600 mg 400 mg 600 mg	Oral suspension (Stick Pack) Film-coated tablets	 2001	 Generic	
Prednisone	5 mg	Tablets	2004	Generic	Dacortin® (Merck)
	30 mg 10 mg			Hybrid	



Cardiovascular

Ambrisentan	5 mg 10 mg	Tablets Unidose	2018	Generic	Volibris® (GSK)
Digoxin	0.25 mg/m(2ml) 0.25 mg	Solution for injection (Ampoule) Tablets	2010	Well established use	Lanoxin® (Roche)
Furosemide	40 mg	Tablets	2004	Generic	Seguril® (Sanofi)
Hydrochlorothiazide	25 mg 50 mg	Tablets	2011	Generic	Hidrosaruletil® (Chiesi)



AVAILABLE PRODUCTS



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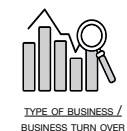
QUALITY COMMITMENT

PRODUCT	STRENGTH	PHARMACEUTICAL FORM	DATE OF DOSSIER DEVELOPMENT	TYPE OF APPLICATION	INNOVATOR BRAND
Rivaroxaban <i>(New)</i>	10 mg 15 mg 20 mg	Film-coated tablets	2021	Generic	Xarelto® (Bayer)
Irbesartan	75 mg 150 mg 300 mg	Film-coated tablets	2008	Generic	Aprovel® (Sanofi)
Irbesartan/HCTZ	150/12.5 mg 300/12.5 mg 300/25 mg	Film-coated tablets	2009	Generic	Coaprovel® (Sanofi)
Labetalol	5 mg/ml 100 mg 200 mg	Solution for injection (Ampoule) Tablets	2010	Well established use	N/A
Propranolol	10 mg 40 mg	Tablets	2017	Generic	Sumial® (Astra Zeneca)
Rosuvastatin	5 mg 10 mg 20 mg 40 mg	Film-coated tablets	2014	Generic	Crestor® (Astra Zeneca)



C.N.S.

Aripiprazole	5 mg	Tablets	2014	Generic	Abilify® (Bristol Myers Squibb)
	10 mg				
	15 mg				
	30 mg	Orodispersible tablet			
	10 mg				
	15 mg				
Betahistine	1 mg/ml	Oral solution			
	8 mg	Tablets	2009	Generic	Serc® (Abbot)
	16 mg		2019		
24 mg			Betaserc® (Abbot)		



PRODUCT	STRENGTH	PHARMACEUTICAL FORM	DATE OF DOSSIER DEVELOPMENT	TYPE OF APPLICATION	INNOVATOR BRAND
Bromazepam	1.5 mg 3 mg	Capsules	2008	Generic Well established use	Lexatin® (Roche)
Donepezil	5 mg 10 mg	Film-coated tablets	2012	Generic	Aricept® (Pfizer)
Lorazepam	2.5 mg 5 mg	Tablets	2007 2014	Generic	Orfidal® (Wyeth Farma)
Lormetazepam <i>(New)</i>	0,5 mg 1 mg 2 mg	Tablets	2008	Generic	Noctamid® (Bayer)
Memantine <i>(New)</i>	5 mg 10 mg 15 mg 20 mg 10 mg/ml	Tablets Oral solution	2022 2010 2022 2010 2010	Generic	Axura® (Merz Pharma)
Naloxone	0.4 mg/ml	Solution for injection (Ampoule)	2007	Innovator	N/A
Pregabalin	25 mg 50 mg 75 mg 100 mg 150 mg 200 mg 225 mg 300 mg	Capsules	2011	Generic	Lyrica® (Pfizer)



Contraceptives

Etonogestrel Ethinylestradiol	0.120 mg 0.015 mg	Vaginal delivery system	2017	Generic	Nuvaring® (MSD)
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Gastrointestinal

Metoclopramide

1mg/ml

Oral solution

2020

Generic

Primperan®
(Sanofi Syntebalo)



Musculoskeletal

Naproxeno Sodium

550 mg

Film-coated tablets

2020

Generic

Antalgin®
(Atrahs Pharma)

Vitamin D3

2.000 IU/ml
10.000 IU/ml
25.000 IU/ml
50.000 IU/ml

Oral solution

2019
2020
2017
2019

Well established use

Kern Pharma S.L.
Deltius® (Italfarmaco)
Kern Pharma S.L.



Oncology

Imatinib

100 mg
400 mg

Film-coated tablets

2014

Generic

Glivec® (Novartis)

Letrozole

2.5 mg

Tablets

2007

Generic

Femara® (Novartis)
(Sanofi Syntebalo)



Oral Antidiabetics

Vildagliptin

50 mg

Tablets

2016

Generic

Galvus® (Novartis)

Sitagliptin

25 mg
50 mg
100 mg

Film-coated tablets

2020

Generic

Janovia® (MSD)



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Respiratory System

Cold relief Paracetamol Chlorphenamine Dextromethorphan Pseudoephedrine	500 mg 2 mg 15 mg 30 mg	Capsules	2019	Well established use	Frenadol® (Johnson & Johnson)
Paracetamol Codeine	500 mg 30 mg	Tablets	2009	Generic	Cod Efferalgan® (BMS)
Hedera Helix	35 mg 5 ml	Oral Suspension (Stick Pack) Bottles 100ml- 200ml	2022	Well established use	Prospantus® (Ferrer)



Urology

Finasteride	1 mg 5 mg	Tablets	2011	Generic	Propecia® (Merck) Proscar® (Merck)
Solifenacin	5 mg 10 mg	Film-coated tablets	2017	Generic	Vesicare® (Astellas)
Tadalafil	5 mg 10 mg 20 mg	Film-coated tablets	2017	Generic	Cialis® (Lilly)



Venous System

Diosmin/Hesperidin (Flavonoic Fraction)	450/50 mg 900/100 mg	Tablets	2017 2019	Well established use	Daflon® (Servier)
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QUALITY COMMITMENT



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AVAILABLE PRODUCTS



QUALITY COMMITMENT

EU GMP



GCC GMP



PQ SINTHESYS GMP



UNE-EN ISO 14001





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CALIER



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www.kernpharma.com

Polígono Ind. Col II. Venus, 72 08228, Barcelona, Spain