



**KERN**  
**P H A R M A**

**INTERNATIONAL PRODUCT LIST**

PRODUCT	STRENGTH	PHARMACEUTICAL FORM	DATE OF DOSSIER DEVELOPMENT	TYPE OF APPLICATION	INNOVATOR BRAND
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GASTROINTESTINAL

Metoclopramide	1mg/ml	Oral solution (Flask)	Q3 2020	Generic	Primperan® (Sanofi Syntebalo)
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MUSCULOSKELETAL

Naproxen sodium	550 mg	Film-coated tablets	Q1 2020	Generic	Antalgin® (Atrnabs Pharma)
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Vitamin D3	20.000 IU	Soft capsules	Q2 2020	To be defined	Deltius® (Italfármaco)
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ORAL ANTIDIABETICS

Sitagliptin	25 mg 50 mg 100 mg	Film-coated tablets	Q3 2020	Generic	Januvia® (MSD)
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RESPIRATORY SYSTEM

Hedera Helix Syrup	35mg/5ml	Oral solution (Stick pack & Flask)	Q4 2020	Well established use	Own development
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VENOUS SYSTEM

Rivaroxaban	10 mg 15 mg 20 mg	Film-coated tablets	Q1 2022	Generic	Xarelto® (Bayer)
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<b>ANALGESICS</b>					
<b>Fentanyl</b>	100 mcg 200 mcg 300 mcg 400 mcg 600 mcg 800 mcg	Sublingual tablets	2017	Generic	Abstral® (Prostakan)
<b>Paracetamol</b>	500 mg 650 mg 1 g	Oral solution (Stick Pack)	2014	Well established use Generic	N/A
<b>Paracetamol</b>	500 mg 650 mg 1 g	Tablets	2005	Well established use Generic	Gelocatil® (Ferrer)
<b>ANTIFUNGALS</b>					
<b>Ketoconazole</b>	20 mg/g	Cream	2017	Hybrid	Ketoisdin® (Isdin)
<b>ANTIINFECTIVES</b>					
<b>Azithromycin</b>	500 mg	Film-coated tablets	2000	Generic	Zitromax® (Pfizer)
<b>Clarithromycin</b>	250 mg 500 mg	Film-coated tablets	2001	Generic	Klacid® (Abbot)
<b>ANTIINFLAMATORIES</b>					
<b>Dexamethasone (without preservatives)</b>	4 mg/ml	Solution for injection	2019	Generic	Fortecortin® (Merck)
<b>Diclofenac</b>	23.2 mg/g	Gel	2019	Hybrid	Voltadol Forte® (GSK)

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Diclofenac	11.6 mg/g	Gel	2008	Hybrid	Voltadol® (GSK)
Ibuprofen	200 mg 400 mg 600 mg	Oral suspension (Stick Pack)	2014	Hybrids	Neobrufen® (Abbot)
Ibuprofen	400 mg 600 mg	Film-coated tablets	2001	Generic (400 mg)	Neobrufen® (Abbot)
Prednisone	5 mg 30 mg	Tablets	2004	Generic	Dacortin® (Merck)
	10 mg			Hybrid	Dacortin® (Merck)
					
Ambrisentan	5 mg 10 mg	Tablets Unidose	2018	Generic	Volibris® (GSK)
Propranolol	10 mg 40 mg	Tablets	2017	Generic	Sumial® (Astra Zeneca)
Digoxin	0.25 mg/ml (2ml)	Solution for injection	2010	Well established use	N/A
Digoxin	0.25 mg	Tablets	2010	Well established use	N/A
Furosemida	40 mg	Tablets	2004	Generic	Seguril® (Sanofi)
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)

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Labetalol	5 mg/ml	Solution for injection	2010	Well established use	N/A
Rosuvastatin	5 mg 10 mg 20 mg 40 mg	Film-coated tablets	2014	Generic	Crestor® (Astra Zeneca)
					
Aripiprazole	5 mg 10 mg 15 mg 30 mg	Tablets	2014	Generic	Abilify® (Bristol Myers Squibb)
Aripiprazole	1 mg/ml	Oral solution	2014	Generic	Abilify® (Bristol Myers Squibb)
Betahistine	24 mg  8 mg 16 mg	Tablets	2019	Generic	Betaserc® (Abbot)  Serc® (Abbot)
Bromazepam	1.5 mg 3 mg	Capsules	2008	Generic Well established use	Lexatin® (Roche)
Diazepam	2.5 mg 5 mg 10 mg 25 mg	Tablets	2010	Well established use	N/A
Lorazepam	1 mg 2.5 mg 5 mg	Tablets	2014	Generic	Orfidal® (Wyeth Farma)

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Lormetazepam	0.5 mg 1 mg 2 mg	Tablets	2008	Generic	Noctamid® (Bayer)
Memantine	10 mg 20 mg	Tablets	2010	Generic	Ebixa® (Lundbeck)
Memantine	10 mg/ml	Oral solution	2010	Generic	Ebixa® (Lundbeck)
Naloxone	0.4 mg/ml	Solution for injection	2010	Innovator	N/A
Pregabalin	25 mg 50 mg 75 mg 100 mg 150 mg 200 mg 300 mg	Capsules	2011	Generic	Lyrica® (Pfizer)
Sulpiride	50 mg	Capsules	2005	Generic	Dogmatil® (Sanofi)
<b>CONTRACEPTIVES</b>					
Etonogestrel Ethinylestradiol	0.120 mg 0.015 mg (per 24 hours)	Vaginal delivery system	2017	Generic	Nuvaring®
<b>MUSCULOSKELETAL</b>					
Chondroitin sulfate	400 mg	Capsules	2014	Generic	Condrosan® (Bioiberica)

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Vitamin D3	2.000IU/ml	Oral solution	2019	Well established use	Kern Pharma S.L.
Vitamin D3	25.000IU/ml	Oral solution	2019	Well established use	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)

## ORAL ANTIDIABETICS

Vildagliptin	50 mg	Tablets	2016	Generic	Galvus® (Novartis)
Vildagliptin/Metformin <small>*Only available in certain countries</small>	50/850 mg 50/1000 mg	Film-coated tablets	2019	Generic	Eucreas® (Novartis)
Sitagliptin/Metformin <small>*Only available in certain countries</small>	50/850 mg 50/1000 mg	Film-coated tablets	2019	Generic	Janumet® (MSD)

## RESPIRATORY SYSTEM

Cold relief capsules Paracetamol Chlorphenamine Dextromethorphan Pseudoephedrine	500 mg 2 mg 15 mg 30 mg	Capsules	2019	Well established use	Frenadol® (Johnson & Johnson)
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# DRUG PRODUCTS AUDITABLE & ROUTINE

PRODUCT	STRENGTH	PHARMACEUTICAL FORM	DATE OF DOSSIER DEVELOPMENT	TYPE OF APPLICATION	INNOVATOR BRAND
 <b>UROLOGY</b>					
<b>Solifenacin</b>	5 mg 10 mg	Film-coated tablets	2017	Generic	Vesicare® (Astellas)
<b>Tadalifo</b>	5 mg 10 mg 20 mg	Film-coated tablets	2017	Generic	Cialis® (Lilly)
 <b>VENOUS SYSTEM</b>					
<b>Diosmin/Hesperidin (FFP)</b>	450/50 mg	Tablets	2017	Well established use	Daflon® (Servier)
<b>Diosmin/Hesperidin (FFP)</b>	900/100 mg	Tablets	2019	Well established use	Daflon® (Servier)
<b>Diosmin/Hesperidin</b>	450/50 mg	Tablets	2008	Well established use	Daflon® (Servier)



