



**FENNHEALTHCARE**  
Live longer and healthier



**FENNHEALTHCARE**

Presentation  
Jan. 2020

# HIGHLIGHTS

- ❑ FENNHEALTHCARE is a privately held European pharmaceutical group operating worldwide
  - ✔ Headquarters in Ireland and affiliate in Spain
  - ✔ Owner of TORREFARMA (Spain) and ZAPHYR (Switzerland)
  - ✔ Dedicated strong local teams / appointed commercial partners and sub-distributors worldwide, operating in 50 countries
  
- ❑ In-license, and commercialize high Quality FDA/ European approved innovative products & quality branded generics in highly specialized disease. FENNHEALTHCARE is
  - ✔ The only company operating strongly in emerging markets with high focus on oncology / Haematology among other highly specialized disease areas with an existing, established portfolio
  - ✔ Flexible commercialization models to ensure our Partners optimize their license and supply agreements, regulatory service agreements, market access, marketing, sales and/or volume commitments
  
- ❑ FENNHEALTHCARE maintains best-in-class capabilities across key corporate functions including Regulatory Affairs, Medical Affairs, Pharmacovigilance, Supply Chain, Sales and Marketing within a fully compliant, audited model. We have;
  - ✔ A seasoned international team with strong regional track record
  - ✔ Local teams (Medical liaisons, sales managers, product specialists and Key account managers) and sub-distributors that are highly recognized and well-connected with key stakeholders in the region
  - ✔ Compliant processes in place that fulfil all legal and regulatory EU (and local/national) frameworks

# VISION, MISSION & VALUES

## □ Our Vision & Mission

- Our vision is to build FENNHEALTHCARE into a leading specialty pharmaceutical company, with a strong and successful presence across the Emerging Markets (META, LATAM and ASIA).
- We are committed to improving people's lives through our innovative solutions as well as high quality affordable medicines in key disease areas.

## □ Our Values :

At FENNHEALTHCARE, how we do business is as important as what we do. We seek to build trust-based and lasting relationships with our many stakeholders.

### ▪ **Ensure Quality**

We focus on delivering high quality products and services ensuring value for patients, stakeholders and partners.

### ▪ **Drive for Excellence**

We make swift and quality decisions required to take our business forward, and execute with focus and determination. We value empowerment, courage and trustworthiness in all our activities and partnerships.

### ▪ **Respect & Ethics :**

We show consideration for one another, recognizing each other's differences, needs and expectations. We comply with applicable laws, regulations and our internal code of conduct.



# International Product List

Product

Pharmaceutical Form

Strength

Innovator Brand



## ONCOLOGY

Anastrozole

Tablets

1 mg

ARIMIDEX

Capecitabine

Tablets

150/500 mg

XELODA

Docetaxel

Concentrate for  
solution for infusion

20/80/160 mg  
(20 mg/ml)

TAXOTERE

# International Product List

Product

Pharmaceutical Form

Strength

Status dossier

Innovator Brand



## ONCOLOGY

**Imatinib**

Capsules

100/400 mg

"√ EU MA granted and EU eCTD available  
√ Supply available  
√ EU MA for immediate transfer available  
√ Tech Transfer available"

GLEEVEC

**Letrozole**

Tablets

2.5 mg

"√ EU MA granted and EU eCTD available  
√ Tech Transfer available"

FEMARA

**Oxaliplatin**

Concentrate for solution for infusion

50/100/200 mg (5 mg/ml)

"√ EU MA granted and EU eCTD available  
√ Supply available"

ELOXATIN

**Paclitaxel**

Concentrate for solution for infusion

30/100/300 mg (6 mg/ml)

"√ EU MA granted and EU eCTD available  
√ Supply available"

TAXOL

# International Product List

Product

Pharmaceutical Form

Strength

Status dossier

Innovator Brand



## ANTIBIOTICS

Clarithromycin

Lyophilized  
for injection

500 mg/vial

"√ EU MA granted and EU  
eCTD available  
√ Tech Transfer available"

BIAXIN

Colistimethate  
Sodium

Lyophilized  
for injection

1/2 MIU/vial

"√ EU MA pending but EU  
eCTD available  
√ Supply available  
√ Tech Transfer available"

COLIMYCIN

# International Product List

Product

Pharmaceutical Form

Strength

Status dossier

Innovator Brand



## CARDIOVASCULAR

**Atorvastatin**

Tablets

10/20/40 mg

"√ EU MA granted and EU eCTD available  
√ Tech Transfer available"

LIPITOR

**Irbesartan**

Tablets

75/150/300 mg

"√ EU MA granted and EU eCTD available  
√ Tech Transfer available"

AVAPRO,  
APROVEL,  
KARVEA

**Irbesartan +  
Hydrochlorothiazide**

Tablets

150mg+12.5mg  
300mg+12.5mg

"√ EU MA granted and EU eCTD available  
√ Tech Transfer available"

AVAPRO,  
APROVEL,  
KARVEA

# International Product List

Product

Pharmaceutical Form

Strength

Status dossier

Innovator Brand



## CARDIOVASCULAR

Rivaroxaban

Tablets

10/15/20 mg

"√ Product in development  
√ EU MA pending"

XARELTO

Telmisartan

Tablets

20/40/80 mg

"√ EU MA granted and EU eCTD available  
√ EU MA for immediate transfer available  
√ Tech Transfer available"

MICARDIS



## C.N.S.

Donepezil

Tablets

5/10 mg

"√ EU MA granted and EU eCTD available  
√ Supply available  
√ Tech Transfer available"

ARICEPT

# International Product List

Product

Pharmaceutical Form

Strength

Status dossier

Innovator Brand



C.N.S.

**Quetiapine**

Immediate  
release tablets

25/50/100/150  
200/300/400 mg

"√ EU MA granted and EU  
eCTD available  
√ Tech Transfer available"

SEROQUEL

**Quetiapine**

Slow release tablets

50/150/200  
/300/400 mg

"√ EU MA granted and EU  
eCTD available  
√ Tech Transfer available"

SEROQUEL

**Irbesartan +  
Hydrochlorothiazide**

Tablets

150mg+12.5mg  
300mg+12.5mg

"√ EU MA granted and EU  
eCTD available  
√ Tech Transfer available"

AVAPRO,  
APROVEL,  
KARVEA

# International Product List

Product

Pharmaceutical Form

Strength

Status dossier

Innovator Brand



C.N.S.

Rivastigmine

Capsules

1.5/3/4.5/6 mg

"√ EU MA granted and EU eCTD available  
√ Supply available  
√ Tech Transfer available"

EXELON

Rivastigmine

Oral Solution

2 mg/ml

"√ EU MA granted and EU eCTD available  
√ Supply available  
√ EU MA for immediate transfer available  
√ Tech Transfer available"

EXELON

# International Product List

Product

Pharmaceutical Form

Strength

Status dossier

Innovator Brand



## GASTROENTERAL

Pantoprazole

Lyophilized  
for injection

40 mg/vial

"√ EU MA granted and EU  
eCTD available  
√ EU MA for immediate  
transfer available  
√ Tech Transfer available"

PROTONIX



## PAIN

Paracetamol +  
Tramadol

Tablets

325+ 37,5 mg

"√ EU MA granted and EU  
eCTD available  
√ Tech Transfer available"

ZALDIAR

# International Product List

## PRODUCT

## PRESENTATION

## REFERENCE

ALIMENTARY TRACT & METABOLISM		
Cholecalciferol D3 Vitamin	80 000 IU, oral solution in 2 ml ampoules	Zyma D® (Rottapharm)
Cholecalciferol D3 Vitamin	200 000 IU, oral solution in 2 ml ampoules	Zyma D® (Rottapharm)
Racecadotril	10 mg, 30 mg, granules for oral solution in sachets	Tiorfan® (Bioprojet Pharma)
Metronidazole	250 mg, 500 mg film-coated tablets	Flagyl® (Sanofi)
Ursodeoxycholic Acid (UDCA)	250 mg, 500 mg film-coated tablets	Delursan® (Aptalis Pharma)
ANTINEOPLASIC & ANTIBIOTIC		
Mitomycin	20 mg lyophilized powder in vial	Mitomycin-C® (Kyowa) / Mitem® (Vygoris)
ANTIPARASITIC		
Ivermectin	3 mg tablets	Stromectol® (MSD)
CARDIOVASCULAR SYSTEM		
Midodrine	2.5 mg, 5 mg tablets	Gutron® (Nycomed)
Urapidil	30 mg, 60 mg, 90 mg capsules	Ebrantil®, Eupressyl® (Altana Pharma)
CENTRAL NERVOUS SYSTEM		
Duloxetine	20 mg, 30 mg, 40 mg, 60 mg gastro resistant capsules	Cymbalta®, Yentreve® (Lilly)
Etifoxine	50 mg, capsules	Stresam® (Biocodex)
Hydroxyzine	25 mg scored film-coated tablets	Atarax® (UCB Pharma)
Zolpidem	5 mg, 10 mg orodispersible tablets	Stilnox® (Sanofi)

Product availability is subject to patent restrictions in countries where applicable patents are in force.

# International Product List

## PRODUCT

## PRESENTATION

## REFERENCE

DERMATOLOGICAL		
Amorolfine	5% nail lacquer 2.5 ml, 3 ml, 5 ml bottles	Loceryl® (Galderma International)
Clobetasol	500 µg shampoo, 125 ml bottles	Clobex® (Galderma International)
Dexpanthenol	5% ointment 30 g, 100 g tubes	Bepanthen® (Bayer Santé Familiale)
Glycerol / Vaseline / Paraffin	15% / 2% / 8% cream, 250 g tubes	Dexeryl® (Pierre Fabre Médicament)
Ketoconazole	2 % cream, 20 g tubes	Ketoderm® (Janssen Cilag)
Mupirocin	2 % ointment, 15 g tubes	Bactroban® (GSK) / Mupiderm® (Almirall)

GENITO-URINARY SYSTEM		
Fenticonazole	600 mg, vaginal soft gelatin capsules	Lomexin® (Effik)
Sertaconazole	300 mg, vaginal ovules	Monazol® (Theramex)

RESPIRATORY SYSTEM		
Ebastine	10 mg, 20 mg orodispersible tablets	Kestinlyo® (Almirall)
Levocetirizine	5 mg orodispersible tablets	Xyzall® (UCB Pharma)
Mometasone furoate monohydrate	50 µg/dose, nasal spray 60, 120, 140 doses	Nasonex® (Schering Plough)
Rupatadine	10 mg tablets	Wystamm® (J Uriach & Cia)

Product availability is subject to patent restrictions in countries where applicable patents are in force.

# International Product List - Product Pipeline

## PRODUCT

## PRESENTATION

## REFERENCE

ALIMENTARY TRACT & METABOLISM			
Esomeprazole	20 mg, 40 mg, delayed release pellets in capsules	Q1 2020	Nexium® / Inexium® (Astrazeneca)
Cholecalciferol D3 Vitamin	10 000 IU/ml, oral solution, drops, in 10 ml bottles	Q3 2020	Zyma D® (Rottapharm)
Ursodeoxycholic Acid (UDCA)	250 mg, capsules	Q3 2020	Ursofalk® (Dr Falk Pharma GmbH)

ANTI-INFLAMMATORY			
Flurbiprofen	100 mg film coated tablets	Q3 2020	Antadys® (Theramex)
Fludrocortisone	50 µg scored tablets	Q3 2020	Flucortac® (HPAP - HAC Pharma)

CENTRAL NERVOUS SYSTEM			
Methocarbamol	500 mg tablets	Q1 2020	Lumirelax® (Juvisé Pharmaceuticals)
Methocarbamol	750 mg film coated tablets	Q1 2020	Methocarbamol FCT 750mg® (Recordati)

DERMATOLOGICAL			
Bifonazole	1 % cream, 15 g tubes	Q3 2020	Amycor® (Merck Sante)
Clobetasol	0,05 % cream, 10 g tubes	Q3 2020	Dermoval® (Laboratoire GlaxoSmithKline)

RESPIRATORY SYSTEM			
Fluticasone furoate	27,5 µg/dose, nasal spray, 120 doses	Q3 2020	Veramyst® (Laboratoire GlaxoSmithKline)
Triamcinolone acetonide	55 µg/dose, nasal spray, 120 doses	Q2 2020	Nasacort® (Sanofi Aventis France)

Product availability is subject to patent restrictions in countries where applicable patents are in force.