

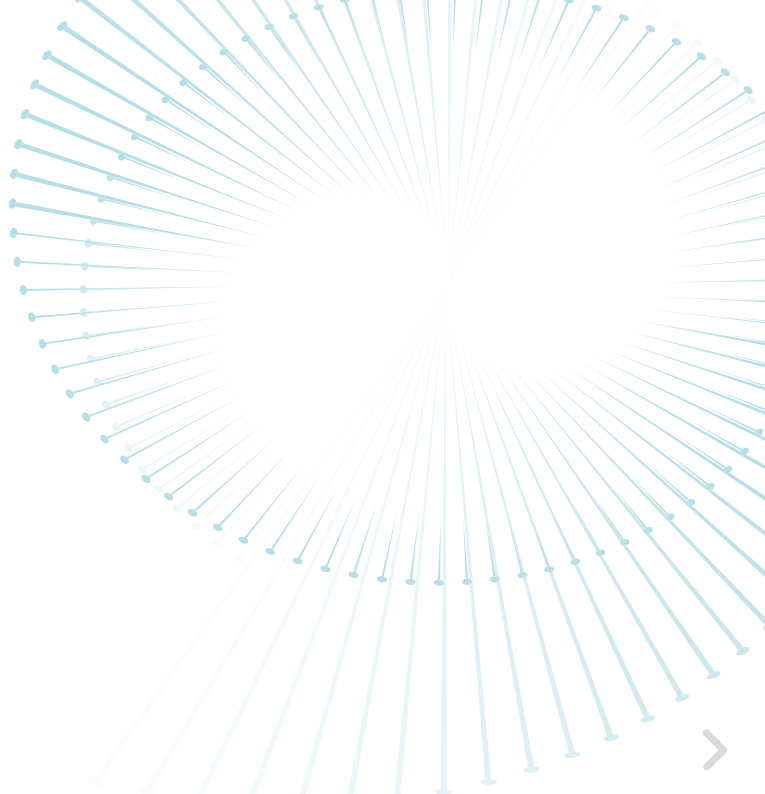
# PRODUCT LIST

2022



medichem

50 years



## GENERICs FDFs

Available Dossiers

Dossiers Under Development

Dossiers Under Consideration

## GENERICs APIs

Available Portfolio - Malta

Available Portfolio - Spain

Under Development

## CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

FDFs





AVAILABLE DOSSIERS

| MOLECULE                                                                                                 | PHARMACEUTICAL FORM & STRENGTH                                                | REFERENCE PRODUCT                    | INDICATION                                                                  | DOSSIER STATUS                                |
|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------|-----------------------------------------------------------------------------|-----------------------------------------------|
|  Apixaban               | Film-coated tablets 2.5 mg, 5 mg                                              | Eliquis® BMS/Pfizer                  | Stroke and systemic embolism<br>Deep vein thrombosis and pulmonary embolism | Approved: US, EU, UK                          |
|  Captopril              | Tablets<br>12.5 mg, 25 mg, 50 mg, 100 mg                                      | Captopril Mylan                      | Hypertension<br>Heart failure                                               | Approved: US                                  |
| Daptomycin                                                                                               | Powder for solution for injection<br>or infusion in glass vial 350 mg, 500 mg | Cubicin® Merck                       | Skin and soft-tissue infections<br>Endocarditis                             | Approved: CA, EU, UK, KR, UA, AU<br>Filed: ZA |
|  Mirtazapine            | Tablets 7.5 mg, 15 mg, 30 mg and 45 mg                                        | Remeron® Organon                     | Major depression                                                            | Filed: US, EU                                 |
|  Prucalopride Succinate | Film-coated tablets 1 mg, 2 mg                                                | Resotrans® Janssen<br>Resolor® Shire | Chronic constipation                                                        | Approved: EU and UK,<br>US filing NCE: Dec'23 |
|  Rivaroxaban            | Film-coated tablets<br>2.5 mg, 10 mg, 15 mg, 20 mg                            | Xarelto® Bayer                       | Stroke and systemic embolism<br>Deep vein thrombosis and pulmonary embolism | Approved: EU, CIS<br>Filed: IL, MX            |
| Sodium Oxybate                                                                                           | Oral Solution in bottle 300 mg/ml                                             | Xyrem® UCB Pharma                    | Narcolepsy                                                                  | Approved: EU                                  |
|  Sugammadex Sodium    | Solution for injection<br>200 mg / 2 ml<br>500 mg / 5 ml                      | Bridion® MSD                         | Reversal of neuromuscular blockade in anesthesia                            | Approved: EU, UK, NZ<br>Filed: IL, MX         |
|  Sunitinib Maleate    | Capsules<br>12.5 mg, 25 mg, 37.5 mg, 50 mg                                    | Sutent® Pfizer                       | Renal carcinoma,<br>pancreatic and stromal tumors                           | Approved: EU, SA.<br>Filed: MX                |
| Thalidomide                                                                                              | Capsules 50 mg                                                                | Thalidomid Celgene®<br>Celgene       | Multiple myeloma                                                            | Approved: EU, UK                              |
| Tobramycin                                                                                               | Nebulizer solution in plastic<br>ampoule blow-fill-seal 300 mg / 5 ml         | Tobi® Novartis                       | Cystic fibrosis                                                             | Approved: AU, EU, UK, BR, PA,<br>GT, NZ, US   |



## DOSSIERS UNDER DEVELOPMENT

|    | MOLECULE                  | PHARMACEUTICAL FORM     | STRENGTH                               | REFERENCE PRODUCT           | INDICATION                                              | DOSSIER READINESS |
|----|---------------------------|-------------------------|----------------------------------------|-----------------------------|---------------------------------------------------------|-------------------|
|    | Axitinib                  | Film coated tablets     | 1 mg and 5 mg                          | Inlyta®                     | Advance renal cell carcinoma                            |                   |
| HP | Dexmedetomidine           | Infusion bag            | 4 mcg/ml                               | Precedex® Pfizer            | Sedation of patients during treatment in intensive care | Q2 2022           |
| ⬡  | Edaravone                 | Solution for infusion   | 30 mg / 100 ml<br>60 mg / 100 ml       | Radicava® Mitsubishi Tanabe | Amyotrophic lateral sclerosis                           | Q4 2022 (NCE)     |
| ⬡  | Revefenacin               | Solution for inhalation | 175 mcg / 3 ml                         | Yupelri® Mylan              | Chronic obstructive pulmonary disease (COPD)            | Q4 2022 (NCE-1)   |
| ⬡  | Ruxolitinib               | Tablets                 | 5 mg, 10 mg, 15 mg,<br>20 mg and 25 mg | Jakafi® Novartis            | Myelofibrosis,<br>polycythemia vera                     | Q2 2024           |
| ⬡  | Varenicline<br>L-tartrate | Tablets                 | 0.5 mg and 1 mg                        | Chantix®, Champix® Pfizer   | Smoking cessation                                       | Q4 2022           |

## DOSSIERS UNDER CONSIDERATION

|  | MOLECULE            | PHARMACEUTICAL FORM | STRENGTH       | REFERENCE PRODUCT | INDICATION           |
|--|---------------------|---------------------|----------------|-------------------|----------------------|
|  | Tofacitinib citrate | Film coated tablets | 5 mg and 10 mg | Xeljanz®          | Rheumatoid arthritis |



## AVAILABLE PORTFOLIO - MALTA

|                                                                                             |                                                                                                |                                                                                                       |
|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
|  Apixaban  | Micafungin Sodium                                                                              | Solifenacin Succinate                                                                                 |
| Cinacalcet HCl                                                                              |  Prucalopride |  Sugammadex Sodium |
| Desvenlafaxine Succinate                                                                    | Rasagiline Tartrate                                                                            |  Sunitinib Malate  |
|  Edaravone |  Rivaroxaban  | Vildagliptin                                                                                          |
| Lofexidine New!                                                                             | Saxagliptin HCl                                                                                |                                                                                                       |

## AVAILABLE PORTFOLIO - SPAIN

|                                                                                               |                                                                                                  |                                                                                                              |
|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Adapalene                                                                                     | Fluvoxamine Maleate                                                                              | Olopatadine HCl                                                                                              |
| Asenapine Maleate                                                                             |  Guanfacine HCl | Paroxetine HCl                                                                                               |
| Brimonidine Tartrate                                                                          | Lamotrigine                                                                                      | Pazopanib                                                                                                    |
|  Captopril | Loxapine Base                                                                                    | Pimecrolimus                                                                                                 |
| Clozapine                                                                                     | Loxapine Succinate                                                                               | Quetiapine Fumarate                                                                                          |
| Cyclobenzaprine HCl                                                                           | Mexiletine HCl                                                                                   |  Varenicline L-tartrate |
| Desvenlafaxine Base                                                                           |  Mirtazapine  |                                                                                                              |
| Felodipine                                                                                    | Nepafenac [sterile and non sterile]                                                              |                                                                                                              |



UNDER DEVELOPMENT

|   | ACTIVE PHARMACEUTICAL INGREDIENT | REFERENCE PRODUCT              | INDICATION                                   | DOSSIER READINESS |
|---|----------------------------------|--------------------------------|----------------------------------------------|-------------------|
|   | Opicapone                        | Ongentys®                      | “Off” episodes in Parkinson                  | DMF Q3 2023       |
|   | Relugolix                        | Orgovyx®                       | Prostate cancer and uterine fibroid bleeding | DMF Q4 2023       |
| ⬡ | Revefenacin                      | Yupelri®, Theravance Biopharma | Chronic obstructive pulmonary disease (COPD) | DMF Q2 2022       |
|   | Voclosporin                      | Lupkynis®                      | Lupus Nephritis                              | DMF Q1 2024       |
| ⬡ | Ruxolitinib                      | Jakafi®, Novartis              | Myelofibrosis, polycythemia vera             | DMF Q2 2024       |



## CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

### API - ANTISEPTICS - AVAILABLE

|                                        |     |                               |     |
|----------------------------------------|-----|-------------------------------|-----|
| Chlorhexidine Base                     |     | Chlorhexidine Diacetate       | CEP |
| Chlorhexidine Digluconate 20% Solution | CEP | Chlorhexidine Dihydrochloride | CEP |
| Octenidine Dihydrochloride             | DMF |                               |     |



## FDFs - PHARMACEUTICAL GRADE

### CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

| PRODUCT                                | STRENGTH | FORMATS AVAILABLE  |                                                  |
|----------------------------------------|----------|--------------------|--------------------------------------------------|
| Hydroalcoholic solution<br>Transparent | 0.50%    | Plastic<br>bottles | 30 ml, 100 ml, 250 ml<br>More formats on request |

### CHLORHEXIDINE DIGLUCONATE - UNDER DEVELOPMENT DOSSIERS

|                                                     |       |                    |                                                  |
|-----------------------------------------------------|-------|--------------------|--------------------------------------------------|
| Hydroalcoholic solution<br>Coloured                 | 0.50% | Plastic<br>bottles | 30 ml, 100 ml, 250 ml<br>More formats on request |
| Hydroalcoholic solution<br>Transparent and coloured | 2%    | Plastic<br>bottles | 30 ml, 100 ml, 250 ml<br>More formats on request |



## CHLORHEXIDINE AND OTHER ANTISEPTICS

### FDFs - PHARMACEUTICAL GRADE

#### OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

| PRODUCT | STRENGTH                            | FORMATS AVAILABLE |      |
|---------|-------------------------------------|-------------------|------|
| Spray   | 2% phenoxyethanol + 0,1% octenidine | Plastic bottles   | 50ml |



### FDFs - COSMETIC GRADE

#### OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

| PRODUCT | FORMATS AVAILABLE                 |       |
|---------|-----------------------------------|-------|
| Cream   | Bottle with pump<br>biodegradable | 500ml |





## CHLORHEXIDINE AND OTHER ANTISEPTICS

### FDFs - BIOCIDES GRADE

#### CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

| PRODUCT                                             | STRENGTH | FORMATS AVAILABLE                              |                                                                      |
|-----------------------------------------------------|----------|------------------------------------------------|----------------------------------------------------------------------|
| Hydroalcoholic solution<br>Transparent and coloured | 2%       | Plastic bottles                                | 60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml                         |
|                                                     | 0.50%    |                                                | More formats on request                                              |
| Aqueous solution                                    | 2%       | Blow-fill-seal ampoules<br>and plastic bottles | Single dose (10 ml), 60 ml, 75 ml, 100 ml,<br>125 ml, 250 ml, 500 ml |
|                                                     | 0.50%    |                                                | 10 ml, 60 ml, 75 ml                                                  |
| Wipes                                               |          | Individual sachet                              |                                                                      |
| Aqueous                                             | 2%       | Flow pack of 8 wipes                           | 20 x 20 cm, 6 x 7 cm                                                 |
| Alcoholic                                           |          | Individual sachet                              |                                                                      |
| Hand scrub                                          |          |                                                |                                                                      |
| Transparent                                         | 4%       | HDPE bottles with<br>dosing pump               | 20 ml, 500 ml, 1000 ml                                               |

## Visit Medichem



<https://www.medichem.es/>

## Connect with Medichem



Medichem S.A.



Medichem Manufacturing  
(Malta) Ltd.



Medichem

## Reach out the team today



[bd@medichem.es](mailto:bd@medichem.es)