

Yes
You
Health

# Product list

September 2026

Farmaprojects

polpharma GROUP

# Under development

## Complex Injectables

| INN | PHARMACEUTICAL FORM | STRENGTH | REFERENCE PRODUCT | DOSSIER AVAILABILITY & MARKET SCOPE |
|---|---|---|---|---|
| Alimentary Tract & Metabolism | | | | |
| Setmelanotide | Solution for injection | 10 mg/mL | Imcivree® (Rhythm Pharmaceuticals) | EU: Q1 2030<br>US: Q1 2030 |
| Tirzepatide | Solution for injection | 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg | Mounjaro® (Lilly) | EU: Q4 2032 |
| Cardiovascular System | | | | |
| Inclisiran | Solution for injection (pre-filled syringe) | 284 mg / 1.5 mL (189 mg/mL) | Leqvio® (Novartis) | EU: Q3 2028** |
| Endocrinology | | | | |
| Etelcalcetide | Solution for injection | 5 mg/mL | Parsabiv® (Amgen) | EU: Q4 2027 |
| Nervous System | | | | |
| Nusinersen* | Solution for injection | 12 mg / 5 mL vial (2.4 mg/mL) | Spinraza® (Biogen) | EU: Q2 2027** |

## Other Generics

| INN | PHARMACEUTICAL FORM | STRENGTH | REFERENCE PRODUCT | DOSSIER AVAILABILITY & MARKET SCOPE |
|---|---|---|---|---|
| Alimentary Tract & Metabolism | | | | |
| Empagliflozin* / Metformin | Film - coated tablets | 5 mg / 850 mg<br>5 mg / 1000 mg<br>12.5 mg / 850 mg<br>12.5 mg / 1000 mg | Synjardy® (Boehringer Ingelheim) | EU: Q1 2027 |
| Allergy / Immunology | | | | |
| Baricitinib* | Film - coated tablets | 1 mg, 2 mg, 4 mg | Olumiaant® (Lilly) | EU: Q1 2027<br>CA: Q1 2027 |
| Ruxolitinib | Cream | 15 mg/g | Opzelura® (Incyte) | EU: Q1 2028 |
| Upadacitinib*** | Prolonged - release tablets | 15 mg, 30 mg, 45 mg | Rinvoq® (Abbvie) | EU: Q4 2028 |
| Cardiovascular System | | | | |
| Bempedoic Acid | Film - coated tablets | 180 mg | Nilemdo® (Esperion, Daiichi Sankyo ) | EU: Q2 2027 |
| Bempedoic Acid / Ezetimibe | Film - coated tablets | 180 mg / 10 mg | Nustendi® (Esperion, Daiichi Sankyo ) | EU: Q3 2027 |
| Bempedoic Acid / Ezetimibe/Atorvastatin | Film - coated tablets | 180 mg / 10 mg / 20 mg<br>180 mg / 10 mg / 40 mg<br>180 mg / 10 mg / 80 mg | Nustendi® (Daichii Sankyo) / Lipitor® (Pfizer) | EU: Q3 2028 |
| Finerenone | Film - coated tablets | 10 mg, 20 mg, 40 mg | Kerendia® (Bayer) | EU: Q2 2027 (10 mg , 20 mg)<br>CA: Q3 2027 (10 mg , 20 mg)<br>EU: Q3 2028 (40 mg) |
| Finerenone FDC - iSGLT-2 (Empagliflozin*) | Film - coated tablets | 10 / 10mg<br>20 / 10mg | Kerendia® (Bayer) / Jardiance® (Boehringer Ingelheim) | EU: Q3 2029 |

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*Based on exemption under art.5(2) of the Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products Apixaban, Dapagliflozin, Empagliflozin, Empagliflozin + Metformin, Linagliptin and Nusinersen, which are protected by SPCs, can be manufactured and offered only for the purpose of export to non-EU countries, provided all requirements of the Regulation are met.*
**Polpharma Group API*
***G: Available for Global deals*
****Partnership between Polpharma and Egis*

| INN | PHARMACEUTICAL FORM | STRENGTH | REFERENCE PRODUCT | DOSSIER AVAILABILITY & MARKET SCOPE |
|---|---|---|---|---|
| Cardiovascular System | | | | |
| Finerenone FDC - iSGLT-2 (Dapagliflozin*) | Film - coated tablets | 10 / 10mg<br>20 / 10mg | Kerendia® (Bayer) / Forxiga® (AstraZeneca) | EU: Q3 2029 |
| Valsartan | Film - coated tablets | 40 mg, 80 mg, 160 mg, 320 mg | Diovan® (Novartis) | EU: Q4 2027 |
| Valsartan / Hydrochlorothiazide | Film - coated tablets | 80 mg / 12.5 mg<br>160 mg / 12.5 mg<br>160 mg / 25 mg<br>320 mg / 12.5 mg<br>320 mg / 25 mg | Codiovan® (Novartis) | EU: Q1 2028 |
| Central Nervous System | | | | |
| Cenobamate | Film - coated tablets | 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, 200 mg | Ontozry® (SK Biopharmaceuticals) | EU: Q1 2028 |
| Cenobamate | Oral solution (first-in-market) | 10 mg/mL | Ontozry® (SK Biopharmaceuticals) | EU: Q3 2028 |
| Dermatology | | | | |
| Minoxidil OTC | Foam | 5% | Regaine® (Johnson&Johnson) | EU: Q1 2028 |
| Endocrinology | | | | |
| Osilodrostat | Tablets | 1 mg, 5 mg, 10 mg | Isturisia® (Recordati) | EU: Q2 2028 |
| Respiratory System | | | | |
| Fluticasone / Vilanterol | Inhalation powder | 92 mcg / 22 mcg<br>184 mcg / 22 mcg | Bro Ellipta® (GSK) | EU: Q1 2028<br>CA: Q1 2028 |
| Fluticasone / Umeclidinium / Vilanterol | Inhalation powder | 100 mcg / 74.2 mcg / 62.5 mcg<br>200 mcg / 74.2mcg / 62.5 mcg | Trelegy Ellipta® (GSK) | EU: Q3 2028 |
| Oxymetazoline OTC | Nasal gel | 0.25 mg/g, 0.5 mg/g | Oxalin® (Polpharma) | EU: Q3 2028 |
| Umeclidinium / Vilanterol | Inhalation powder | 55 mcg / 22 mcg | Anoro Ellipta® (GSK) | EU: Q2 2028<br>CA: Q2 2028 |
| Xylometazoline OTC | Nasal gel | 0.1 mg/g, 1 mg/g | Otrivin® (Novartis) | EU: Q2 2027 |
| Xylomethazoline / Dexpanthenol OTC | Nasal spray solution | 1.0 mg / 50 mg/mL (10 mL)<br>0.5 mg / 50 mg/mL (10 mL) | Nasic® (Cassella-med) | EU: Q1 2028 |

# Available Generics

| INN | PHARMACEUTICAL FORM | STRENGTH | REFERENCE PRODUCT | MARKET SCOPE | LACTOSE FREE | STABILITY | SHELF LIFE |
|---|---|---|---|---|---|---|---|
| Alimentary Tract & Metabolism | | | | | | | |
| Dapagliflozin* / Metformin | Film - coated tablets | 5 mg / 850 mg<br>5 mg / 1000 mg | Xigduo® (AstraZeneca) | EU<br>CA | Yes | II: available<br>IVb: available | 36 months |
| Dapagliflozin* | Film - coated tablets | 5 mg, 10 mg | Forxiga® (AstraZeneca) | EU<br>CA | Yes | II: available<br>IVb: available | 36 months |

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|---|---|---|---|---|---|---|---|
| **Alimentary Tract & Metabolism** | | | | | | | |
| Empagliflozin* | Film - coated tablets | 10 mg, 25 mg | Jardiance® (Boehringer Ingelheim) | EU<br>CA | Yes | II: available<br>IVb: available | 36 months<br>36 months / Do not store above 30 °C |
| Linagliptin* | Film - coated tablets | 5 mg | Trajenta® (Boehringer Ingelheim) | EU<br>CA | Yes | II: available<br>IVb: available | 36 months |
| Orlistat | Hard capsules | 120 mg | Xenical® (Roche) | EU | Yes | II: available<br>IVb: not available | 24 months |
| Orlistat OTC | Hard capsules | 60 mg | Alli® (GSK) | EU | Yes | II: available<br>IVb: not available | 24 months |
| Sitagliptin* | Film - coated tablets | 25 mg, 50 mg, 100 mg | Januvia® (Merck) | EU | Yes | II: available<br>IVb: available | 36 months |
| Sitagliptin* / Metformin | Film - coated tablets | 50 mg / 850 mg<br>50 mg / 1000 mg | Janumet® (Merck) | EU | Yes | II: available<br>IVb: available | 24 months |
| **Anti-Infectives for Systemic Use** | | | | | | | |
| Aciclovir | Tablets | 200 mg, 400 mg, 800 mg | Zovirax® (GSK) | EU | Yes | II: available<br>IVb: not available | 36 months |
| **Antineoplastic & Immunomodulating Agents** | | | | | | | |
| Apremilast* | Film - coated tablets | 10 mg, 20 mg, 30 mg | Otezla® (Celgene) | EU<br>CA | Yes | II: available<br>IVb: not available | 36 months |
| **Blood & Blood Forming Organs** | | | | | | | |
| Apixaban* | Film - coated tablets | 2.5 mg, 5 mg | Eliquis® (Bristol-Myers Squibb) | EU | No | II: available<br>IVb: available | 36 months |
| Rivaroxaban* | Film - coated tablets | 2.5 mg, 10 mg, 15 mg, 20 mg | Xarelto® (Bayer) | EU<br>CA | No | II: on-going<br>IVb: on-going | 24 months |
| Rivaroxaban* | Capsules | 10 mg, 15 mg, 20 mg | Xarelto® (Bayer) | EU | No | II: available<br>IVb: not available | 24 months |
| Ticagrelor* | Film - coated tablets | 60 mg, 90 mg | Brilique® (AstraZeneca) | EU | Yes | II: available<br>IVb: available | 36 months |
| **Cardiovascular System** | | | | | | | |
| Hydrochlo-rothiazide* | Tablets | 12.5 mg, 25 mg, 50 mg | Esidrex® (Novartis) | EU | No | II: available<br>IVb: not available | 60 months |
| Ramipril | Tablets | 2.5 mg, 5 mg, 10 mg | Delix® (Sanofi) | EU | No | II: available<br>IVb: not available | 36 months |
| Ramipril / Amlodipine | Hard capsules | 5 mg / 5 mg<br>5 mg /10 mg<br>10 mg / 5 mg<br>10 mg / 10 mg | Tritace® /Ramipril (Sanofi) & Norvasc®/ Amlodipine (Pfizer) | EU | Yes | II: available<br>IVb: not available | 36 months |
| Ramipril / Indapamide | Hard capsules (IR dosage form) | 5 mg / 2.5 mg<br>10 mg / 2.5 mg<br>5 mg / 1.25 mg<br>10 mg / 1.25 mg | Delix® (Sanofi) / Lozol® (Sanofi) | EU | No | II: available<br>IVb: not available | 36 months |

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|---|---|---|---|---|---|---|---|
| **Cardiovascular System** | | | | | | | |
| Rosuvastatin | Film - coated tablets | 5 mg, 10 mg, 20 mg | Crestor® (AstraZeneca) | EU | No | II: available<br>IVa: available<br>IVb: not available | 36 months (Zone II)<br>12 months (Zone IVa) |
| Telmisartan / Amlodipine | Bilayered tablets | 40 mg / 5 mg<br>40 mg / 10 mg<br>80 mg / 5 mg<br>80 mg / 10 mg | Twynsta® (Boehringer Ingelheim) | EU | Yes | II: available<br>IVb: available | 36 months |
| **Dermatology** | | | | | | | |
| Dimetindene | Gel | 1 mg/g (20 g)<br>1 mg/g (30 g)<br>1 mg/g (50 g) | Fenistil(TM) (Novartis) | EU | Yes | II: available<br>IVb: available | 36 months |
| **Genito-Urinary System & Sex Hormones** | | | | | | | |
| Tadalafil* | Film - coated tablets | 2.5 mg, 5 mg, 10 mg, 20 mg | Cialis® (Eli Lilly) | EU | No | II: available<br>IVb: available | 48 months |
| **Gynecology** | | | | | | | |
| Progesterone | Solution for injection | 25 mg / 1.112 mL | Lubion® (IBSA) | EU | Yes | II: available<br>IVb: not available | 18 months |
| **Musculoskeletal System** | | | | | | | |
| Paracetamol / Ibuprofen | Film - coated tablets | 500 mg / 200 mg | Nurofen Ultima® (Reckitt Benckiser) | EU | Yes | II: available<br>IVb: on-going | 36 months |
| **Nervous System** | | | | | | | |
| Dimethyl Fumarate | Gastro - resistant hard capsules | 120 mg, 240 mg | Tecfidera® (Biogen Idec) | EU<br>CA | Yes | II: available<br>IVb: available | 48 months / do not store above 30°C (zone II)<br>24 months / do not store above 30°C (zone IV) |
| Memantine hydrochloride | Film - coated tablets | 10 mg, 20 mg | Ebixa® (Lundbeck) | EU | No | II: available<br>IVa: available | 36 months |
| Quetiapine | Film - coated tablets | 25 mg, 100 mg, 150 mg, 200 mg, 300 mg | Seroquel® (AstraZeneca) | EU | No | II: available<br>IVb: available | 36 months |
| **Respiratory System** | | | | | | | |
| Glycopyrronium | Inhalation powder | 44 mcg | Seebri Breezhaler® (Novartis) | EU | No | II: available<br>IVb: not available | 24 months |
| Glycopyrronium / Indacaterol | Inhalation powder | 43 mcg / 85 mcg | Ultibro Breezhaler® (Novartis) | EU | No | II: available<br>IVb: available | 24 months |
| **Vitamins & Minerals** | | | | | | | |
| Cholecalciferol (Vitamin D3) | Soft capsule | 20.000 IU | N/A | EU | Yes | II: available<br>IVa: not available | 36 months |

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*Reported by clients representing 70% of our business.*

FARMAPROJECTS SAU
Carrer Provença 392, 6ª Planta
08025 Barcelona (Spain)
Phone +34 93 508 05 00
email: sales@farmaprojects.com

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