

## BA-BE Dosage Form Experience (India)

### **INJECTION: 40 (26 PIVOTAL & 14 PILOT)**

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- Enoxaparin Sodium 100mg/1ml SC Injection
- Medroxyprogesterone Acetate
- 'depo-provera<sup>®</sup>' 150 mg/ml Injectable Suspension
- Pegfilgrastim 6 mg SC Injection
- Darbepoetin 60/40µg IVInjection 6 SCInjection
- Repoitin Injection l0000IU/mL IV-Injection
- Darbepoetin alfa 0.75 µg/kg SC/IV Injection
- Repoitin Injection l0000IU/mLSC-Injection
- Octreotide Acetate 30 mg Injectable Suspension-USFDA - Fast-Pilot
- Adalimumab 40 mg SC Injection
- Glucagon lmg/vial For injection-USFDA - Fast-Pivotal
- Progesterone 25 mg Injection-EMA - Fast-Pivotal
- AryoTrust (Trastuzumab) 150 mg Powder for IV cone. Solution - EU Pivotal
- Enoxaparin Sodium 80 mg Injection (PFS)
- Enoxaparin Sodium 40 mg/0.4ml Injection
- Amphotericin B Liposome 50 mg Injection
- Diclofenac Sodium 37.5 mg/ml Injection
- Diclofenac Sodium 37.5 mg/ml Injection
- Iron Sucrose (20 mg/mL) 100 mg Injection
- Leuprorelin Acetate 3.75 mg SC Injection
- Meloxicam 15 mg/ml (Dose - 30 mg) Injection
- Paclitaxel 100 mg/vial (260 mg/m<sup>2</sup>) Injectable Suspension
- Paclitaxel 100 mg/vial at a dose of 260 mg/m<sup>2</sup> Injectable Suspension
- Paliperidone Palmitate 156mg/ml Injection
- Triamcinolone Acetonide 40 mg/ml Injectable Suspension

### **SUBLINGUAL: 22 (16 PILOT & 06 PIVOTAL)**

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- Asenapine Maleate 'Saphris<sup>®</sup>' 10mg Sublingual Tablets
- Nitroglycerin 0.6mg Sublingual tablets
- Zolpidem 3.5 mg Sublingual Tablets

### **CHEWABLE TABLETS: 31 (16 PILOT & 15 PIVOTAL)**

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- Montelukast Sodium 5 mg Chewable Tablets
- Norethindrone / Ethinyl Estradiol 0.4/0.035 mg x 2 Chewable Tablets
- Norethindrone acetate+EE Chewable Tablets 1mg/0.02mg
- Mebendazole 100mg Chewable Tablet
- Carprofen 25 mg Chewable Tablets
- Deracoxib 25 mg Chewable Tablets
- Famotidine, Calcium Carbonate, Magnesium 10, 800, 165 mg Tablets-Chewable
- Lamotrigine 200 mg Chewable Tablets.
- Methylphenidate Hydrochloride 40 mg ER Chewable
- Norethindrone /ethinyl Estradiol 0.8/0.025 mg Chewable
- Norethindrone Acetate and Ethinyl Estradiol 1.0 mg/10 mcg
- Norethindrone Acetate and Ethinyl Estradiol/ Ferrous Fumarate 1mg/0.02mg/75mg

### **SUSPENSION: 160 (76 PILOT & 84 PIVOTAL)**

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- Atovaquone 750 mg/5ml Suspension
- Azithromycin 200 mg/5 ml Oral Suspension
- Deferasirox 500mg Tablets for Oral Suspension
- Esomeprazole 40mg DR Oral Suspension
- Metronidazole 200mg/5ml Oral Suspension
- Oxcarbazepine 300mg/5ml oral suspension
- Simvastatin 40mg/5ml Oral Suspension
- Amoxicilin+Clavulanic Acid 400/57mg/ml Suspension
- Amoxicillin/Clavulanate Potassium 600/42.9mg/5ml Oral Suspension
- Nitrofurantoin 25 mg/5 ml Oral Suspension
- Oseltamivir Phosphate 6 mg/ml Suspension
- Amoxi+Clavul250/62.5mg/5mLSuspension
- Ibuprofen Suspension 100mg/5ml
- Naproxen Oral Sus USP, 125 mg/5 ml
- Bosentan 32 mg for Oral Suspension
- Sildenafil l0mg/mL Oral Suspension
- Ursodiol 250mg/5 ml Oral Suspension

- Sulfamethoxazole and Trimethoprim 200 mg/40 mg/5 ml
- Oral Suspension-USFDA - Fast-Pilot
- Metronidazole Benzoate 200 mg/5 mL Oral Suspension
- Amoxicillin/ Clavulanic Acid Powder 875 mg/ 125 mg powder for oral suspension
- Acyclovir Suspension 200 mg/mL Suspension
- Amlodipine Benzoate 1 mg/mL Oral Suspension
- Atorvastatin 4mg/ml (40 mg/ 10 mL) oral suspension
- Azathioprine 20 mg/mL suspension
- Baclofen 5 mg/ML Oral Suspension
- Carbamazepine 100 mg/5 mL Oral Suspension
- Clarithromycin 250 mg/5 mL oral suspension
- Eltrombopag 25 mg oral suspension
- Felbamate 600 mg/5mL Suspension
- Lenalidomide 25 mg/5ml Oral Suspension
- Methylphenidate Hydrochloride 25mg/5mL ER Suspension
- Metronidazole Benzoate 200 mg/5 mL Oral Suspension
- Mirabegron 8mg/ml Oral Suspension
- Mycophenolate Mofetil 200 mg/m Oral Suspension
- Rufinamide 40 mg/mL Oral Suspension
- Spironolactone 25 mg/5mL Oral Suspension
- Ticagrelor 18 mg/ml (90 mg/5 ml) oral suspension

#### **GRANULES: 21 (13 PILOT & 08 PIVOTAL)**

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- Montelukast Sodium 4 mg Oral Granules
- Deferasirox 360 mg Granules
- Mesalamine 2000 mg ER Granules
- Ivacaftor 75 mg/packet Oral Granules

#### **RECTAL: 8 (05 PILOT & 03 PIVOTAL)**

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- Hydrocortisone Acetate 'Cortifoam®' 10% Rectal Foam
- Mesalamine 1000 Mg Rectal Suppositories
- Indomethacin 50 mg/100 mg Suppository-USFDA - Fast-Pivotal

#### **TRANSDERMAL: 156 (114 PILOT 42 PIVOTAL)**

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- Clonidine 0.3 mg/ Day Patch
- Diclofenac 200 mg/patch
- Transdermal Delivery Systems
- Estradiol Placebo Transdermal Delivery System Patch
- Fentanyl TDS- Wear 25 µg/hr, 10.5 sq.cm
- Placebo Patch
- Granisetron Transdermal System 3.1 mg/24hrs Patch
- Lidocaine 5%,700 mg Patch
- Nitroglycerin Transdermal 0.6 mg/ hr Patch
- Rivastigmine- wear 9.5 mg/24 Hours Patch- Hill Top
- Norelgestromin/ethinyl
- Estradiol 6/0.75mg patch
- Buprenorphine TDS 20 µg/hr Patch
- CLONIDINE 0.1 mg/ Day Patch
- Norelgestromin And Ethinyl Estradiol 150/35 mcg per day Transdermal System
- Norelgestromin And Ethinyl Estradiol 4.86 mg/0.264 mg Transdermal System
- Norelgestromin, Ethinyl Estradiol 4.86, 0.264 mg Transdermal
- Norelgestromin/ Ethinyl Estradiol 150/35 mcg Transdermal Patch
- Norelgestromin/ethinyl Estradiol (skin Irritation/sensitization) 150 mcg/35 mcg per day Transdermal System
- Rotigotine 2mg/24 hours Transdermal System
- Scopolamine 1.0 mg over 3 days Transdermal System
- Vehicle Tds (Placebo For Scopolamine) 1 mg/3 days transdermal
- Nitroglycerin Transdermal Infusion Systems 0.4 mg/ hr Patch
- Norelgestromin/ethinyl Estradiol 6/0.75mg patch
- Norelgestromin/ethinyl Estradiol 150/35mcg/day Patch

- Rivastigmine 13.3 mg/24 hours Patch
- Rivastigmine 4.6 mg/24 hours Patch
- Buprenorphine 10 µg/hr Patch
- Buprenorphine Transdermal System 20 µg/hr Patch
- Clonidine 0.1 mg/ Day Patch
- Diclofenac Epolamine 1.3% Topical Patch

#### **VAGINAL: 10 (03 PILOT & 07 PIVOTAL)**

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- Estradiol 'Vagifem<sup>®</sup>' 10 µg Vaginal Tablet
- Estradiol 'Vagifem<sup>®</sup>' 0.01% Vaginal Cream
- Metronidazole 0.75% Vaginal Gel

#### **NASAL SPRAY: 04 (02 PILOT & 02 PIVOTAL)**

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- Olopatadine Hydrochloride 665 mcg/spray
- Methylcobalamin 500µg Nasal Spray
- ALDP 001 (Alcaftadine Nasal Spray 0.25 % & Alcaftadine. Nasal Spray 0.50%)

#### **GEL: 13 (06 PILOT & 07 PIVOTAL)**

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- Diclofenac 1% Gel
- Metronidazole 0.75% Vaginal Gel
- Dapsone 5% Topical Gel
- Clindamycin + Anhydrous Benzoyl Peroxide (Steady State) 10 Mg/G + 50 Mg/G Gel
- Dapsone 7.5% Gel
- Estradiol 0.06% Gel
- Estradiol 0.1% Transdermal Gel

#### **LOTION: (04 PILOT)**

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- Clobetasol Propionate 0.05% Lotion

#### **INHALATION AEROSOL : 14 (09 PILOT & 05 PIVOTAL)**

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- Albuterol Sulfate 90 mcg Albuterol/met dose
- Budesonide/formoterol Fumarate Dihydrate 160 µg /4.5 µg inhalation
- Fluticasone Propionate HFA 220 µg per Actuation Inhalation Aerosol
- Indacaterol/glycopyrronium 85 micrograms/43 micrograms Inhalation Powder, Hard Capsule
- Indacaterol/glycopyrronium 110mcg/50mcg inhalation powder, hard capsules
- Ipratropium Bromide HFA 21µg (4 x 21 µg dose) Inhalation Aerosol

#### **TOPICAL CREAM : 04 (02 PILOT & 01 PIVOTAL)**

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- Spironolactone 5% Topical Cream
- Doxepin Hydrochloride 5% Cream
- Ivermectin 1% Cream