

# API PRODUCT LIST

(MARCH 2024 UPDATE)



| API Name                        | Proprietary Name                           | Main Indication                        | Route, Dosage Form  | Status |        | NCE                        |
|---------------------------------|--|--|---|--------|--------|----------------------------|
|                                 |  |  |   | R&D    | US DMF |                            |
| <b>Abaloparatide</b>            | Tymlos                                     | Osteoporosis                           | <b>Injectable:</b> Solution (subcutaneous)                          | ✓      |        | Expired                    |
| <b>Afamelanotide</b>            | Scenesse                                   | increase pain-free light exposure      | <b>Implant</b> (subcutaneous)                                       | ✓      |        | <b>10/8/2024</b>           |
| <b>Aripiprazole Lauroxil</b>    | Aristada, Aristada Initio Kit              | Antipsychotic (schizophrenia)          | <b>Injectable:</b> ER IM Susp. (in kit: prefilled syringes)         | ✓      |        | Expired                    |
| <b>Aripiprazole Monohydrate</b> | Abilify Maintena                           | Antipsychotic                          | <b>Injectable:</b> ER IM Susp.                                      |        | ✓      | -                          |
| <b>Baricitinib</b>              | Olumiant                                   | Autoimmune diseases                    | <b>Oral:</b> Tablets  |        | ✓      | Expired                    |
| <b>Brexanolone</b>              | Zultresso                                  | Antidepressant, Post-Partum Depression | <b>Injectable:</b> IV solution                                      | ✓      |        | <b>6/17/2024</b>           |
| <b>Bupivacaine Base</b>         | Exparel, Posimir                           | Anesthetic                             | <b>Injectable:</b> Liposomal Susp.<br><b>Infiltration:</b> Solution |        | ✓      | -                          |
| <b>Bupivacaine HCl</b>          | Marcaïne HCl, Xaracoll                     | Anesthetic                             | <b>Injectable:</b> Solution<br><b>Implant</b>                       | ✓      |        | -                          |
| <b>Cabazitaxel</b>              | Jevtana Kit                                | Oncologic                              | <b>Injectable:</b> Solution (IV, Kit)                               |        | ✓      | Expired                    |
| <b>Cabotegravir</b>             | Cabenuva Kit                               | Anti-HIV                               | <b>Injectable:</b> Suspension                                       | ✓      |        | <b>1/21/2026</b>           |
| <b>Cannabidiol</b>              | Epidiolex                                  | Anti-epileptic                         | <b>Oral:</b> Solution   |        | ✓      | Expired                    |
| <b>Cantharidin</b>              | Ycanth                                     | Treatment of molluscum contagiosum     | <b>Topical:</b> Solution  | ✓      |        | <b>Expected (07/21/28)</b> |
| <b>Corticotropin</b>            | Acthar Gel (H.P.), Purified Cortrophin Gel | Antiallergic, various                  | <b>Injectable:</b> IM, Subcutaneous                                 | ✓      |        | -                          |
| <b>Dalbavancin HCl</b>          | Davance                                    | Antibacterial                          | <b>Injectable:</b> Powder for IV                                    | ✓      |        | Expired                    |
| <b>Daprodustat</b>              | Jesduvroq                                  | Anemia Treatment                       | <b>Oral:</b> Tablets  | ✓      |        | <b>2/1/2028</b>            |
| <b>Daridorexant HCl</b>         | Quviviq                                    | Sleep disorders                        | <b>Oral:</b> Tablets  | ✓      |        | <b>4/7/2027</b>            |
| <b>Difelikefalin Acetate</b>    | Korsuva                                    | Anti-pruritic                          | <b>Injectable:</b> IV solution                                      |        | ✓      | <b>8/23/2026</b>           |
| <b>Edaravone</b>                | Radicava - Radicava ORS                    | ALS                                    | <b>Oral:</b> Suspension<br><b>Injectable:</b> IV Solution           | ✓      |        | Expired                    |
| <b>Edoxaban Tosylate</b>        | Savaysa                                    | Anti-thrombotic                        | <b>Oral:</b> Tablets  | ✓      |        | Expired                    |
| <b>Elagolix Sodium</b>          | Orilissa, Oriahnn (copackaged)             | Female reproductive System Disorders   | <b>Oral:</b> Tablets, Capsules                                      |        | ✓      | Expired                    |
| <b>Esketamine HCl</b>           | Spravato                                   | Antidepressant                         | <b>Nasal:</b> Spray   |        | ✓      | <b>3/5/2024</b>            |
| <b>Etelcalcetide HCl</b>        | Parsabiv                                   | Kidney Disease                         | <b>Injectable:</b> IV solution                                      | ✓      |        | Expired                    |
| <b>Etrasimod Arginine</b>       | Velsipity                                  | Ulcerative colitis                     | <b>Oral:</b> Tablets  | ✓      |        | <b>10/12/2028</b>          |
| <b>Ferric Carboxymaltose</b>    | Injectafer                                 | Anti-anemic                            | <b>Injectable:</b> IV Solution                                      |        | ✓      | -                          |
| <b>Ferric Derisomaltose</b>     | Monoferic                                  | Anti-anemic                            | <b>Injectable:</b> IV Solution                                      | ✓      |        | -                          |
| <b>Ferric Maltol</b>            | Accrufer                                   | Anti-anemic                            | <b>Oral:</b> Capsules   | ✓      |        | <b>7/25/2024</b>           |

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(MARCH 2024 UPDATE)



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| Gepirone HCl               | Exxua  | Antidepressant              | Oral: ER Tablets   | ✓      |        | 9/22/2028                                |
| Glucagon Synthetic         | Baquisimi, Gvoke                               | Hypoglycemia treatment      | Nasal: Powder<br>Injectable: Pre-filled Syringe  | ✓      |        | -  |
| Ixazomib Citrate           | Ninlaro  | Oncologic                   | Oral: Capsules   |        | ✓      | Expired                                  |
| Lanreotide Acetate         | Somatuline Depot                               | Endocrine Gland Disease     | Injectable: Single Use Syringe (subcutaneous)  |        | ✓      | -  |
| Lasmiditan Succinate       | Reyvow   | Anti-migraine               | Oral: Tablets  |        | ✓      | 1/31/2025                                |
| Latanoprostene Bunod       | Vyzulta  | Glaucoma Treatment          | Ophthalmic: Solution   |        | ✓      | -  |
| Lenvatinib                 | Lenvima  | Oncologic                   | Oral: Capsules   | ✓      |        | Expired                                  |
| Levomilnacipran HCl        | Fetzima  | Antidepressant              | Oral: ER Capsules  |        | ✓      | Expired                                  |
| Lurbinectedin              | Zepzelca                                       | Oncologic                   | Injectable: Lyophilized Powder   | ✓      |        | 6/15/2025                                |
| Mavacamten                 | Camzyos  | Hypertrophic cardiomyopathy | Oral: Capsules   | ✓      |        | 4/28/2027                                |
| Midostaurin                | Rydapt   | Leukemia Treatment          | Oral: Soft Gel Capsules  |        | ✓      | Expired                                  |
| Milnacipran HCl            | Savella  | Fibromyalgia Treatment      | Oral: Tablets  |        | ✓      | -  |
| Octreotide Acetate         | Mycapssa, Sandostatin, Sandostatin LAR, Oclaiz | Acromegaly                  | Injectable: Subcutaneous or IV, Injectable Kit, Subcut. injection depot<br>Oral: DR Capsules |        | ✓      | -<br>Oclaiz<br>PDUFA date:<br>10/21/2024 |
| Omidenepag Isopropyl       | Omlonti  | Glaucoma Treatment          | Ophthalmic: Solution   | ✓      |        | 9/22/2027                                |
| Oxymetazoline HCl          | Rhofade, Upneeq                                | Skin and Eye Diseases       | Topical: Cream<br>Ophthalmic: Solution   | ✓      |        | -  |
| Ozanimod                   | Zeposia  | MS Treatment                | Oral: Capsules   |        | ✓      | 3/25/2025                                |
| Pasireotide Diaspartate    | Signifor                                       | Cushing's Disease           | Injectable: Solution subcutaneous  | ✓      |        | Expired                                  |
| Patiromer Sorbitex Calcium | Veltassa                                       | Hyperkalemia                | Oral: Powder for Suspension  | ✓      |        | Expired                                  |
| Plecanatide                | Trulance                                       | Constipation                | Oral: Tablets  | ✓      |        | Expired                                  |
| Pramlintide Acetate        | Symlin   | Antidiabetic                | Injectable: Solution (subcutaneous, pen)   | ✓      |        | -  |
| Remimazolam Besylate       | Byfavo   | Sedative                    | Injectable: Lyophilized Powder   |        | ✓      | 10/6/2025                                |
| Ribociclib Succinate       | Kisqali  | Oncologic                   | Oral: Tablets  |        | ✓      | Expired                                  |
| Rifaximin                  | Xifaxan  | Antibacterial               | Oral: Tablets  |        | ✓      | -  |
| Rilpivirine                | Cabenuva Kit                                   | Anti-HIV                    | Injectable: Suspension   | ✓      |        | 1/21/2026                                |
| Rimegepant Sulfate         | Nurtec ODT                                     | Antimigraine                | Oral: Oral Disintegrating Tablets  |        | ✓      | 2/27/2025                                |

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(MARCH 2024 UPDATE)



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|                                    |                          |   |  | R&D    | US DMF |                                      |
| <b>Salmon Calcitonin</b>           | Miacalcin                | Calcium metabolism modifier                             | <b>Nasal:</b> Spray<br><b>Injectable:</b> Solution   |        | ✓      | -                                    |
| <b>Selumetinib</b>                 | Koselugo                 | Neurofibromatosis                                       | <b>Oral:</b> Capsules                                | ✓      |        | 4/10/2025                            |
| <b>Semaglutide Recombinant</b>     | Ozempic, Rybelus, Wegovy | Type II diabetes, Obesity                               | <b>Oral:</b> Tablets<br><b>Injectable:</b> Solution  | ✓      |        | Expired                              |
| <b>Setmelanotide Acetate</b>       | Imcivree                 | Obesity   | <b>Injectable:</b> Solution (Subcutaneous)           | ✓      |        | 11/25/2025                           |
| <b>Tapinarof</b>                   | Vtama                    | Psoriasis Treatment                                     | <b>Topical:</b> Cream                                | ✓      |        | 5/23/2027                            |
| <b>Teduglutide</b>                 | Gattex Kit               | Short Bowel Syndrome Treatment                          | <b>Injectable:</b> Solution (subcutaneous)           | ✓      |        | Expired                              |
| <b>Tipiracil HCl /Trifluridine</b> | Lonsurf                  | Anticancer  | <b>Oral:</b> Tablets                                 | ✓      |        | Expired                              |
| <b>Tirbanibulin</b>                | Klisyri                  | Keratosis Treatment                                     | <b>Topical:</b> Ointment                             |        | ✓      | 12/14/2025                           |
| <b>Tirzepatide</b>                 | Mounjaro, Zepbound       | Antidiabetis (Mounjaro)<br>Weight management (Zepbound) | <b>Injectable:</b> Solution (subcutaneous)           | ✓      |        | Mounjaro: 5/13/2027<br>Zepbound: TBD |
| <b>Treprostinil Diolamine</b>      | Orenitram                | Treatment of pulmonary arterial hypertension            | <b>Oral:</b> ER Tablets                              |        | ✓      | -                                    |
| <b>Trilaciclib Dihydrochloride</b> | Cosela                   | Decrease of chemotherapy-induced myelo suppression      | <b>Injectable:</b> Lyophilized Powder (IV)           | ✓      |        | 2/12/2026                            |
| <b>Viloxazine HCl</b>              | Qelbree                  | ADHD Treatment  | <b>Oral:</b> ER Capsules                             | ✓      |        | 4/2/2026                             |
| <b>Voclosporin</b>                 | Lupkynis                 | Lupus Treatment   | <b>Oral:</b> Softgel Capsules                        | ✓      |        | 1/22/2026                            |
| <b>Vonoprazam Fumarate</b>         | Voquezna                 | GI Diseases   | <b>Oral:</b> Tablets                                 | ✓      |        | Expected (5/3/2027)                  |
| <b>Vosoritide</b>                  | Voxzogo                  | Treatment of achondroplasia                             | <b>Injectable:</b> Lyophilized Powder (subcutaneous) | ✓      |        | 11/19/2026                           |
| <b>Xanomeline</b>                  | KartXT                   | Treatment of schizophrenia                              | <b>Oral:</b> Capsules                                | ✓      |        | PDUFA Date: 9/26/2024                |
| <b>Zavegepant HCl</b>              | Zavzpret                 | Antimigraine  | <b>Nasal:</b> Spray                                  | ✓      |        | 3/9/2028                             |
| <b>Zuranolone</b>                  | Zurzuvae                 | Antidepressant, Post-Partum Depression                  | <b>Oral:</b> Capsules                                | ✓      |        | 10/31/2028                           |

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(MARCH 2024 UPDATE)



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| API Name                     | Proprietary Name                        | Main Indication                      | Route, Dosage Form   | Status |        |
|                              |   |                                      |  | R&D    | US DMF |
| <b>Alprostadil</b>           | Muse                                    | Erectile dysfunction                 | <b>Urethral:</b> Suppository   |        | ✓      |
| <b>Azelaic Acid</b>          | Azelex, Finacea                         | Anti-acne; Rosacea                   | <b>Topical:</b> Cream, Foam, Gel   |        | ✓      |
| <b>Bimatoprost</b>           | Durysta, Latisse, Lumigan               | Antiglaucoma<br>Helps eyelash growth | <b>Ophthalmic:</b> Implant - Solution/<br>Drops<br><b>Topical:</b> Solution/ Drops                                       |        | ✓      |
| <b>Carfilzomib</b>           | Kyprolis                                | Oncologic                            | <b>Injectable:</b> Powder for IV   |        | ✓      |
| <b>Carprofen</b>             | Rimadyl (veterinary)                    | NSAID                                | <b>Oral:</b> Caplets, Chewable tablets<br><b>Injectable:</b> Solution  |        | ✓      |
| <b>Ciclopirox Olamine</b>    | Loprox, Penlac                          | Antifungal                           | <b>Topical:</b> Cream, Shampoo,<br>Suspension  |        | ✓      |
| <b>Colchicine</b>            | Colcrys, Gloperba,<br>Lodoco, Mitigare  | Antigout<br>Heart Disease            | <b>Oral:</b> Tablets, Capsules,<br>Suspension  |        | ✓      |
| <b>Desmopressin Acetate</b>  | DDAVP, Stimate                          | Antidiuretic Hormone                 | <b>Oral:</b> Tablets<br><b>Injectable:</b> IV, Subcutaneous<br><b>Nasal:</b> Spray                                       |        | ✓      |
| <b>Dexlansoprazole</b>       | Dexilant                                | Anti-ulcer                           | <b>Oral:</b> DR Capsules   |        | ✓      |
| <b>Diclofenac Epolamine</b>  | Flector, Licart                         | Anti-rheumatic                       | <b>Topical:</b> Transdermal Patches  |        | ✓      |
| <b>Diclofenac Potassium</b>  | Cambia, Zipsor                          | NSAID                                | <b>Oral:</b> Powder for solution, Soft<br>Gel Capsules, Tablets  |        | ✓      |
| <b>Diclofenac Sodium</b>     | Voltaren - Arthrotec-<br>Pennsaid       | NSAID                                | <b>Oral:</b> DR Tablets; ER Tablets<br><b>Ophthalmic:</b> Solution<br><b>Topical:</b> Gel; Solution                      |        | ✓      |
| <b>Difluprednate</b>         | Durezol                                 | Corticosteroid                       | <b>Ophthalmic:</b> Emulsion  |        | ✓      |
| <b>Docetaxel</b>             | Taxotere                                | Oncologic                            | <b>Injectable:</b> IV solution   |        | ✓      |
| <b>Droxidopa</b>             | Northera                                | Cardiovascular                       | <b>Oral:</b> Capsules  |        | ✓      |
| <b>Efinaconazole</b>         | Jublia                                  | Antifungal                           | <b>Topical:</b> Solution   |        | ✓      |
| <b>Etodolac</b>              | Lodine - Lodine XL                      | Anti-rheumatic                       | <b>Oral:</b> Tablets, ER Tablets,<br>Capsules  |        | ✓      |
| <b>Everolimus</b>            | Afinitor, Afinitor Disperz,<br>Zortress | Oncologic; Immuno<br>suppressant     | <b>Oral:</b> Tablets, Tablets for<br>Suspension  |        | ✓      |
| <b>Fesoterodine Fumarate</b> | Toviaz                                  | Urinary Incontinence                 | <b>Oral:</b> ER Tablets  |        | ✓      |
| <b>Flecainide Acetate</b>    | Tambocor                                | Anti-arrhythmic                      | <b>Oral:</b> Tablets   |        | ✓      |
| <b>Ganirelix Acetate</b>     | Antagon                                 | Infertility                          | <b>Injectable:</b> Pre-filled Syringe  |        | ✓      |
| <b>Glipizide</b>             | Glucotrol, Glucotrol XL,<br>Metaglip    | Diabetes                             | <b>Oral:</b> Tablets, ER Tablets   |        | ✓      |
| <b>Icatibant Acetate</b>     | Firazyr                                 | Angioedema                           | <b>Injectable:</b> Pre-filled Syringe<br>(subcutaneous)  |        | ✓      |
| <b>Icosapent Ethyl (EPA)</b> | Vascepa                                 | Hyper triglyceridemia                | <b>Oral:</b> Soft Gel Capsules   |        | ✓      |
| <b>Imiquimod</b>             | Zyclara                                 | Keratosis                            | <b>Topical:</b> Cream  |        | ✓      |
| <b>Indomethacin</b>          | Indocin                                 | Pain Treatment                       | <b>Oral:</b> Suspension, Capsules,<br>ER Capsules<br><b>Rectal:</b> Suppository<br><b>Injectable:</b> Lyophilized Powder |        | ✓      |

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# API PRODUCT LIST

(MARCH 2024 UPDATE)



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|                                  |   |                                  |  | R&D    | US DMF |
| <b>Latanoprost</b>               | Xalatan, Iyuzeh, Rocklatan, Xelpros                       | Glaucoma Treatment               | <b>Ophthalmic:</b> Solution; Emulsion  |        | ✓      |
| <b>Lidocaine Base</b>            | Lidoderm  | Anesthetic                       | <b>Topical:</b> Ointment, Patch  | ✓      |        |
| <b>Lidocaine HCl</b>             | Multiple  | Anesthetic                       | <b>Injectable:</b> Solution<br><b>Ophthalmic:</b> Gel<br><b>Oral:</b> Solution<br><b>Topical:</b> Solution, Jelly  | ✓      |        |
| <b>Loteprednol Etabonate</b>     | Alrex, Eysuvis, Inveltys, Lotemax, Lotemax SM             | Anti-allergy                     | <b>Ophthalmic:</b> Gel, Suspension, Ointment   |        | ✓      |
| <b>Lubiprostone</b>              | Amitiza   | Laxative                         | <b>Oral:</b> Soft Gel Capsules   |        | ✓      |
| <b>Lurasidone HCl</b>            | Latuda  | Antipsychotic                    | <b>Oral:</b> Tablets   |        | ✓      |
| <b>Meloxicam</b>                 | Mobic, Vivlodex   | NSAID                            | <b>Oral:</b> Tablets, Capsules, Suspension   |        | ✓      |
| <b>1% Misoprostol HPMC</b>       | Arthrotec, Cytotec  | Antiulcerant                     | <b>Oral:</b> Tablets, DR Tablets   |        | ✓      |
| <b>Mycophenolate Mofetil</b>     | Cellcept  | Immuno suppressant               | <b>Oral:</b> Tablets, Capsules, Suspension   |        | ✓      |
| <b>Mycophenolate Mofetil HCl</b> | Cellcept  | Immuno suppressant               | <b>Injectable:</b> IV Infusion   |        | ✓      |
| <b>Mycophenolate Sodium</b>      | Myfortic  | Immuno suppressant               | <b>Oral:</b> DR Tablets  |        | ✓      |
| <b>Nepafenac</b>                 | Ilevro, Nevanac   | NSAID                            | <b>Ophthalmic:</b> Solution, Suspension  |        | ✓      |
| <b>Obeticholic Acid</b>          | Ocaliva   | GI Diseases                      | <b>Oral:</b> Tablets   |        | ✓      |
| <b>Paclitaxel</b>                | Abraxane, Taxol   | Oncologic                        | <b>Injectable:</b> IV Solution, Lyophilized Powder for IV  |        | ✓      |
| <b>Paliperidone</b>              | Invega  | Schizophrenia                    | <b>Oral:</b> ER Tablets  |        | ✓      |
| <b>Paliperidone Palmitate</b>    | Invega Sustenna, Invega Trinza, Invega Hafyera            | Schizophrenia                    | <b>Injectable:</b> ER Suspension (IM)  |        | ✓      |
| <b>Prilocaine Base</b>           | Emla, Oraqix  | Local Anesthetic                 | <b>Topical:</b> Cream, Periodontal Gel   |        | ✓      |
| <b>Prilocaine HCl</b>            | Citanest, Citanest Forte, Citanest Forte Dental           | Local Anesthetic                 | <b>Injectable:</b> Solution  | ✓      |        |
| <b>Ranolazine</b>                | Ranexa, Aspruzyo Sprinle                                  | Antianginal                      | <b>Oral:</b> ER Tablets, ER Granules (sachets)   |        | ✓      |
| <b>Risperidone</b>               | Risperdal, Risperdal Consta, Rykindo, Perseris Kit, Uzedy | Antipsychotic                    | <b>Oral:</b> Tablets<br><b>Injectable:</b> Powder for Suspension (IM - subcut.), ER Suspension (prefilled syringe) |        | ✓      |
| <b>Rivastigmine Base</b>         | Exelon  | Dementia treatment               | <b>Transdermal:</b> Patches  |        | ✓      |
| <b>Roflumilast</b>               | Daliresp, Zoryve  | COPD - Psoriasis                 | <b>Oral:</b> Tablets<br><b>Topical:</b> Cream, Foam  |        | ✓      |
| <b>Rotigotine</b>                | Neupro  | Parkinson, Restless Leg Syndrome | <b>Transdermal:</b> Patches  |        | ✓      |
| <b>Rufinamide</b>                | Banzel  | Antiepileptic                    | <b>Oral:</b> Tablets   |        | ✓      |
| <b>Sirolimus</b>                 | Rapamune, Fyarro, Hyftor                                  | Immuno suppressant               | <b>Oral:</b> Tablets, Solution<br><b>Injectable:</b> Powder (IV)<br><b>Topical:</b> Gel                            |        | ✓      |

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|                              |                                  |  |   | R&D    | US DMF |
| <b>Solifenacin Succinate</b> | VESicare, VESicare LS            | Overreactive bladder and other genitourinary system diseases | <b>Oral:</b> Tablet, Suspension   |        | ✓      |
| <b>Spirolactone</b>          | Aldactazide, Aldactone, CaroSpir | Antihypertensive   | <b>Oral:</b> Tablets, Suspension  |        | ✓      |
| <b>Tacrolimus</b>            | Prograf, Protopic, Astragraf XL  | Immuno suppressant (Prograf)<br>Dermatitis (Protopic)        | <b>Oral:</b> Capsules, Granules for Suspension, ER Capsules<br><b>Injectable:</b> Solution (IV)<br><b>Topical:</b> Ointment |        | ✓      |
| <b>Tafluprost</b>            | Zioptan                          | Glaucoma Treatment   | <b>Ophthalmic:</b> Solution   |        | ✓      |
| <b>Tofacitinib Citrate</b>   | Xeljanz, XeljanzXR               | Rheumatoid Arthritis   | <b>Oral:</b> Tablets, ER Tablets, Solution  |        | ✓      |
| <b>Tolterodine Tartrate</b>  | Detrol, Detrol LA                | Overactive Bladder   | <b>Oral:</b> Tablets, ER Capsules   |        | ✓      |

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