

New Drug Approvals

1. Gemmily (ethinyl estradiol and norethindrone acetate) Capsules 0.02 mg / 1 mg

Company: Chemo Research SL

Date of Approval: November 9, 2020

Treatment for: Ethinyl estradiol and norethindrone is used as contraception to prevent pregnancy.

2. Brinzolamide Ophthalmic Suspension 1%

Company: Watson Laboratories Inc.

Date of Approval: November 27, 2020

Treatment for: Brinzolamide ophthalmic (for the eyes) is used to treat certain types of glaucoma and other causes of high pressure inside the eye.

3. Nitazoxanide Tablets 500 mg

Company: Rising Pharma Holdings Inc.

Date of Approval: November 27, 2020

Treatment for: Nitazoxanide is used to treat diarrhea caused by Giardia or Cryptosporidium.

4. Fosfomycin Tromethamine Granules for Oral Solution 3 grams (base)/single-dose sachet

Company: Xiromed Pharma España, SL

Date of Approval: October 6, 2020

Treatment for: Fosfomycin is an antibiotic that fights infection caused by bacteria. Fosfomycin is used to treat bladder infections.

5. Azelaic Acid Topical Foam 15%

Company: Teva Pharmaceuticals USA, Inc.

Date of Approval: October 7, 2020

Treatment for: Azelaic acid topical (for the skin) is used to treat acne and rosacea.

6. Tavaborole Topical Solution 5%

Company: Perrigo Pharma International DAC

Date of Approval: October 13, 2020 -

Treatment for: Tavaborole topical is used to treat a fungal infection of the toenail called onychomycosis.

7. Pomalidomide Capsules 1 mg, 2 mg, 3 mg and 4 mg

Company: Breckenridge Pharmaceutical, Inc.

Date of Approval: October 30, 2020

Treatment for: Pomalidomide is used to treat multiple myeloma (cancer resulting from a progressive blood disease). Pomalidomide is usually given after at least two other medications have been tried without success.

8. Levothyroxine Sodium Capsules 0.075 mg and 0.15 mg

Company: Teva Pharmaceuticals USA, Inc.

Date of Approval: October 28, 2020

Treatment for: Levothyroxine is used to treat hypothyroidism (low thyroid hormone). This medicine is given when your thyroid does not produce enough of this hormone on its own.

9. Lapatinib Ditosylate Tablets 250 mg (base)

Company: Natco Pharma Limited

Date of Approval: September 29, 2020 -

Treatment for: Lapatinib is used to treat advanced hormone-related breast cancer that has progressed or spread after treatment with other cancer medicines. Lapatinib is used for this condition only if your tumor tests positive for a protein called human epidermal growth factor receptor 2 (HER2). HER2 protein can speed the growth of cancer cells.

10. Ciprofloxacin and Dexamethasone Otic Suspension/Drops 0.3% / 0.1%

Company: Dr. Reddy's Laboratories Ltd.

Date of Approval: August 10, 2020

Treatment for: Ciprofloxacin is an antibiotic that treats infections caused by bacteria. Dexamethasone is a steroid. It reduces the actions of chemicals in the body that cause inflammation. Ciprofloxacin and dexamethasone otic (for the ear) is a combination medicine used to treat infections inside the ear (also

called otitis media), and infections of the ear canal (also called otitis externa).

**11. Dimethyl Fumarate Delayed Release Capsules
120 mg and 240 mg**

Company: Mylan Pharmaceuticals, Inc.

Date of Approval: August 17, 2020

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Treatment for: Dimethyl fumarate is used to treat relapsing forms of multiple sclerosis in adults (including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease).

References: www.drugs.com/newdrugs