

# New Drug Update

## INSIDE THIS ISSUE:

New drugs approved by FDA



*Latest formulation*

*Latest drugs*

*Ancient drug –  
new uses*

## PHARMA WINS PRODUCT!!

The purpose of this issue is to provide specialized and consistent source of information regarding the newly approved drugs, to all the Health care professionals.



### Elagolix/Estradiol/Norethindrone acetate and Elagolix

#### Date of Approval



#### Class of drug

Combination of elagolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin.

#### Indication

Heavy menstrual bleeding due to uterine fibroids in premenopausal women

#### Dosage formulation

Capsule

### Minocycline

#### Date of Approval



#### Class of drug

Topical tetracycline

#### Indication

Inflammatory acne  
rosacea -adults

#### Dosage formulation

Topical foam

### Celecoxib

#### Date of Approval



#### Class of drug

NSAID

#### Indication

Acute treatment of  
migraine




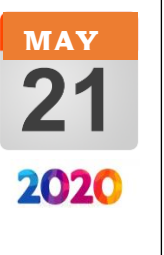

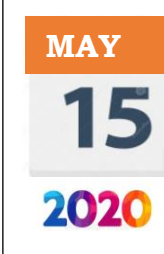
#### Dosage formulation



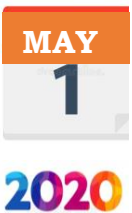
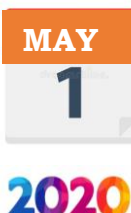
Oral solution

## Do you know?

[FDA drug approval process](#)

Discovery/concept  
Preclinical research  
Clinical research  
FDA review  
FDA post-market  
safety monitoring

Flortaucipir F18		Artesunate	
<b>Date of Approval</b> 	<b>Class of drug</b> Radioactive diagnostic agent  <b>Indication:</b> PET imaging, to estimate the neurofibrillary tangles in adult patients with Alzheimer's disease  <b>Dosage formulation</b> IV injection	<b>Date of Approval</b> 	<b>Class of drug</b> Antimalarial  <b>Indication</b> Initial treatment of severe malaria in adult and paediatric patients  <b>Dosage formulation</b> IV Injection
Lactic & citric acid, K <sup>+</sup> bitartrate		Apomorphine hydrochloride	
<b>Date of Approval</b> 	<b>Class of drug</b> Non hormonal vaginal gel  <b>Indication</b> Contraceptive  <b>Dosage formulation</b> Vaginal gel	<b>Date of Approval</b> 	<b>Class of drug</b> Dopamine agonist  <b>Indication</b> OFF episodes of Parkinson's Disease  <b>Dosage formulation</b> Sublingual film
Fluoroestradiol F18		Ripretinib	
<b>Date of Approval</b> 	<b>Class of drug</b> Radioactive diagnostic agent  <b>Indication</b> PET imaging agent- recurrent /metastatic cancer  <b>Dosage formulation</b> IV injection	<b>Date of Approval</b> 	<b>Class of drug</b> Broad-spectrum KIT and PDGFR $\alpha$ inhibitor  <b>Indication</b> :4 <sup>th</sup> line treatment in GIST  <b>Dosage formulation</b> Tablet

Selpercatinib		Capmatinib	
<b>Date of Approval</b> 	<b>Class of drug</b> Kinase inhibitor  <b>Indication</b> Non-small cell lung cancer, medullary thyroid cancer  <b>Dosage formulation</b> Capsule	<b>Date of Approval</b> 	<b>Class of drug</b> Kinase inhibitor  <b>Indication</b> Metastatic non-small cell lung cancer with MET ex14  <b>Dosage formulation</b> Tablet
Daratumumab and Hyaluronidase-fihj		Leuprolide acetate	
<b>Date of Approval</b> 	<b>Class of drug</b> Combination of daratumumab, a CD38-directed cytolytic antibody & hyaluronidase, an endoglycosidase  <b>Indication</b> Adult patients with multiple myeloma  <b>Dosage formulation</b> Subcutaneous injection	<b>Date of Approval</b> 	<b>Class of drug</b> GnRH agonist  <b>Indication</b> Pediatric patients aged 2 years & older with central precocious puberty  <b>Dosage formulation</b> Injectable suspension

We're on the Web!

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