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A Newsletter on

# CLINICAL PHARMA PRACTICE

An Update on Clinical Research and Drug Information



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## PHARMACIST DESK

### SWINE FLU

Swine influenza is an infection caused by any one of several types of swine influenza viruses. Swine influenza virus (SIV) or swine-origin influenza virus (S-OIV) is any strain of the influenza family of viruses that is epidemic in pigs. As of 2009, the known SIV strains include influenza C and the subtypes of influenza A known as H1N1, H1N2, H2N1, H3N1, H3N2 and H2N3. Swine flu is of the H1N1 influenza subtype of Influenza A.

In 2009, the big difference was that when the swine influenza A virus known as H1N1 first appeared, it was new and most people didn't have any immunity to it. That's why it so easily became a pandemic virus and spread all over the world.

#### Transmission

Swine flu disease spreads among pigs through direct and indirect contact, aerosols, and from infected pigs that do not experience symptoms. The majority of pig to human infections to date have occurred due to the swine virus H3N2 being transmitted directly from pigs to humans, and most of the reported infected people were associated with pig farms. Swine flu spreads from person to person, either by inhaling the virus when an infected person sneezes or coughs, touches surfaces that are contaminated with the virus, then touches the mouth or nose.

#### Symptoms

Symptoms of swine flu, which is caused by the H1N1 virus, are like those of any seasonal flu and include fever, cough, runny nose, sore throat, body aches, chills, and fatigue, diarrhoea and vomiting occasionally, but more commonly seen than with other strains of flu.

### Diagnosis

Laboratory tests include blood tests, chest X-rays, nose or throat swab.

The CDC developed a new kit to diagnose seasonal flu as well as the flu viruses that could become pandemic. This was approved by the FDA (Food and Drugs Administration, USA) in September 2011. It is called the Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel). It gives results in 4 hours.

### Treatment and Vaccine

Treatment is largely supportive and consists of bedrest, increased fluid consumption, cough suppressants, antipyretics and analgesics (eg, acetaminophen, nonsteroidal anti-inflammatory drugs) for fever and myalgias. Severe cases may require intravenous hydration and other supportive measures. Antiviral agents may also be considered for treatment or prophylaxis such as zanamivir and oseltamivir. The nasal H1N1 influenza virus vaccine is a "live virus" vaccine. H1N1 influenza virus vaccine is also available in an injectable form, which is a "killed virus" vaccine.

### Prevention

- ❖ Wash your hands often.
- ❖ Cover your mouth and nose with a tissue when coughing or sneezing.
- ❖ Avoid touching your eyes, nose and mouth.
- ❖ If you've got flu-like symptoms, avoid others until you've been free of fever for 24 hours.
- ❖ Stay at least 6 feet away from people with flu-like illness. If you do wear a face mask, don't reuse it. Face masks should be worn once and then thrown out.

**Ms. CHANDINI S NAIR**, Pharm D Intern,  
Ref : [www.drugs.com](http://www.drugs.com)

## CLINICAL RESEARCH

### New Drug Application for Insomnia Disorder Treatment Lemborexant

Insomnia disorder is characterized by difficulty in falling asleep, staying asleep or both, despite an adequate opportunity to sleep, which can lead to daytime consequences such as fatigue, difficulty in concentrating and irritability. Lemborexant is a novel investigational small molecule compound, that inhibits orexin signaling by binding competitively to both orexin receptor subtypes (orexin receptor 1 and 2). In individuals with normal daily sleep-wake rhythms, orexin signaling is believed to promote periods of wakefulness. In individuals with sleep-wake disorders, it is possible that orexin signaling which regulates wakefulness is not functioning normally, suggesting that inhibiting inappropriate orexin signaling may enable initiation and maintenance of sleep.

A new drug application has been submitted to the U.S. Food and Drug Administration (FDA) for lemborexant, seeking approval for the treatment of insomnia, a sleep-wake disorder. This application was based on the results of two pivotal Phase 3 clinical studies in patients with insomnia. In addition to the treatment of insomnia disorder, a Phase 2 clinical study of lemborexant in patients with irregular sleep-wake rhythm disorder and mild to moderate Alzheimer's dementia is underway.

Ms. Reshma Thomas, Pharm D intern,  
Ref : [www.drugs.com](http://www.drugs.com)

## PHARMA QUIZ

- Which antibacterial drug increases the risk of developing serotonin syndrome?  
a. Trimethoprim    b. Vancomycin    c. Linezolid    d. All of the above
- Many medicines harmlessly discolour urine. Which of the following drug-urine combinations is incorrect?  
a. Nitrofurantoin – Brown    b. Amitriptyline – Blue  
c. Rifampicin – Red    d. None of the above
- Which antiarrhythmic drug class, as they set out in the Vaughan-Williams classification, works chiefly via potassium channel block?  
a. Class Ib /Ic    b. Class II    c. Class III    d. Class IV
- Prolonged use of proton-pump inhibitors is linked to what electrolyte disturbance?  
a. Hyponatraemia    b. Hypokalaemia    c. Hypophosphataemia    d. Hypomagnesaemia
- Which antibacterial drug class does not work by inhibiting protein synthesis?  
a. Aminoglycosides    b. Macrolides  
c. Fluoroquinolones    d. Tetracyclines



Answers : Page 4

Ms. RAJALAKSHMI J, Pharm D Intern,

## RECENTLY APPROVED DRUGS BY CDSCO

S. No.	DRUG NAME	DOSE	DOSAGE	INDICATIONS	APPROVED ON
1.	Revefenacin	175mg	Nebulizer	Chronic obstructive pulmonary disease	11-08-2018
2.	Amifampridine	5mg	Tablet	Lambert- Eaton Myasthenic syndrome	28-11-2018
3.	Prucalopride	2mg	Tablet	Chronic idiopathic constipation	17-12-2018
4.	Calaspargase pegol - mknl	2500 units/m <sup>2</sup>	Injection	Acute lymphoblastic leukaemia	20-12-2018
5.	Ravulizumab - cwvz	300mg/30ml	Injection	Paroxysmal nocturnal hemoglobinuria	21-12-2018
6.	Trastuzumab	4mg/kg	Infusion	Breast cancer, Gastric cancer	18-01-2019
7.	Sumatriptan	10 mg	Nasal spray	Migraine	25-01-2019

Ms. BLESSY PAULSON, Pharm D, Intern,  
Ref: [www.fda.com](http://www.fda.com)

### NEW DRUG PROFILE

#### PRUCALOPRIDE

**CATEGORY :** Prokinetic agent, Serotonin 5HT<sub>4</sub>-receptor agonist

**MECHANISM OF ACTION :** The active substance in is a 5-HT<sub>4</sub> receptor agonist. It works like a substance in the body called 5-hydroxytryptamine. When 5-HT binds to these receptors, it normally stimulates movement in the gut.

**INDICATION :** Treatment of chronic constipation.

**DOSE&DOSAGE :** 2 mg taken once a day. Patients aged over 65 years should start with a 1 mg dose once a day, and this can be increased to 2 mg once a day if needed.

**CONTRAINDICATION :** Hypersensitivity, Renal Impairment requiring dialysis, Intestinal Perforation or Obstruction due to structural or functional disorder of the gut wall, Obstructive Ileus, Severe Inflammatory Conditions of the intestinal tract.

**PRECAUTIONS :** History of Arrhythmias or Ischaemic Cardiovascular Disease.

**ADVERSE REACTIONS :** Diarrhoea, Dizziness, Enlargement of Abdomen or Stomach, Fatigue, Headache, Heart burn

**BRAND NAME :** Pruvict, Resolor

**DRUG APPROVED ON :** December 17, 2018

#### REVEFENACIN

**CATEGORY :** Anticholinergic Agents.

**MECHANISM OF ACTION :** Blocks action of acetylcholine at muscarinic receptors (M1 to M5) in the bronchial airways. It elicits pharmacologic effect by inhibiting M3 at the smooth muscle, leading to bronchodilation.

**INDICATION :** Treatment of Patients With Chronic Obstructive Pulmonary Disease (COPD).

**DOSE & DOSAGE :** 175 mcg inhaled PO qDay via nebulizer using a mouthpiece Administer at the same time every day.

**CONTRAINDICATION :** hypersensitivity to revefenacin. It should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD

**PRECAUTIONS :** Deterioration of disease and acute episodes. Hypersensitivity, Paradoxical bronchospasm, Worsening of narrow-angle glaucoma, Worsening of urinary retention.

**ADVERSE REACTIONS :** cough, nasopharyngitis, upper respiratory tract infection, headache, and back pain.

**BRAND NAME :** Yupelri

**DRUG APPROVED ON :** September 11, 2018

Ms. BLESSY JOY, Pharm D Intern,  
Ref: [www.cdscsco.com](http://www.cdscsco.com)

## DEPARTMENT ACTIVITIES

★ Pharm D interns actively involved in patient Counseling and providing various drug and device related information to patients.

★ Pharm D students actively involved in Ward Rounds and identifying the drug related problems of the patients and its remedy was analysed during case analysis.

### RENAL DOSE ADJUSTMENT CASE

★ A 50 year old male patient with a weight of 64 kg was admitted in General Medicine department.

★ Chief complaints :cough, breathlessness, constipation and abdominal discomfort since 2 days.

★ Past medical history : HTN since 10 years

Past medication history : T.Amlodipine 5mg od

### TREATMENT GIVEN

- ★ T. Prazosin 5mg od
- ★ T. Amlodipine 5 mg od
- ★ T. Folic acid 5 mg
- ★ T. Pantoprazole 40 mg od
- ★ Vitamin d supplements 50 mg od
- ★ T. Calcium Carbonate 500 mg bd
- ★ T. Clonidine 0.1 mg od
- ★ T. Ramipril 5 mg od
- ★ T. Revlamer 400 mg bd
- ★ SYP. Lactulose 10ml hs
- ★ inj. Erythropoietin 4000 U



### COCKROFT - GAULT EQUATION

$$\begin{aligned} \text{Creatinine Clearance} &= (140 - \text{age}) \times \text{body weight} / \text{Scr} \times 72 \\ &= (140 - 50) \times 64 / 11.1 \times 72 \\ &= 7.2 \text{ml / min} \end{aligned}$$

Diagnosis : End Stage Kidney Diseases (stage 5)

### LAB INVESTIGATIONS

S.No.	PARAMETER	PATIENT VALUE	NOMINAL VALUE
1.	Serum Urea	141	14-40mg/dl
2.	Serum Creatinine	11.01	0.6-1.4mg/dl
3.	Proteins	Positive	

### JUSTIFICATION

Recommended dose of Inj. Erythropoietin for a CKD patient is 50U/kg. Here the wt of patient is 64 kg, so only  $64 \times 50 = 3200\text{U}$

### PHARMACIST INTERVENTION

Only 3200 U are needed

DIC ACTIVITIES	NUMBER
No. of Patients Counselling	811
Drug Information Queries Answered	22

Answers for Quiz

1.c      2.d      3.c      4.d      5.c

Book Post

To



Please send your suggestions to  
The Chief Editor

### CLINICAL PHARMA PRACTICE NEWSLETTER

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