

# CHIPS REGIMEN

## VAXCHORA: An Approved Vaccine to prevent Cholera for travellers

The U.S. Food and Drug Administration approved Vaxchora, a vaccine for the prevention of cholera caused by serogroup O1 in adults 18 through 64 years of age traveling to cholera-affected areas. Vaxchora, the only vaccine for the prevention of cholera was approved on June 10th, 2016.

Vaxchora is a live, weakened vaccine that is taken as a single, oral liquid dose of approximately three fluid ounces at least 10 days before travel to a cholera-affected area.

Cholera, a disease caused by *Vibrio cholerae* bacteria, is acquired by ingesting contaminated water or food and causes a watery diarrhea that can range from mild to extremely severe. It is potentially life threatening if treatment with antibiotics and fluid replacement is not initiated promptly. According to the World Health Organization, serogroup O1 is the predominant cause of cholera globally. Travellers to parts of the world with inadequate water and sewage treatment and poor sanitation are at risk for infection. Travellers to cholera-affected areas have relied on preventive strategies recommended by the CDC to protect themselves against cholera, including safe food and water practices and frequent hand washing.

Reference: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm506305.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm506305.htm)

## Coming Soon: 'Artificial Pancreas'

Closed-Loop Insulin-delivery system (Artificial Pancreas) for improving glycemic control and minimizing hypoglycemia in type 1 diabetes are advancing rapidly, including iterations that deliver insulin alone, insulin with glucagon, or glucagon alone.

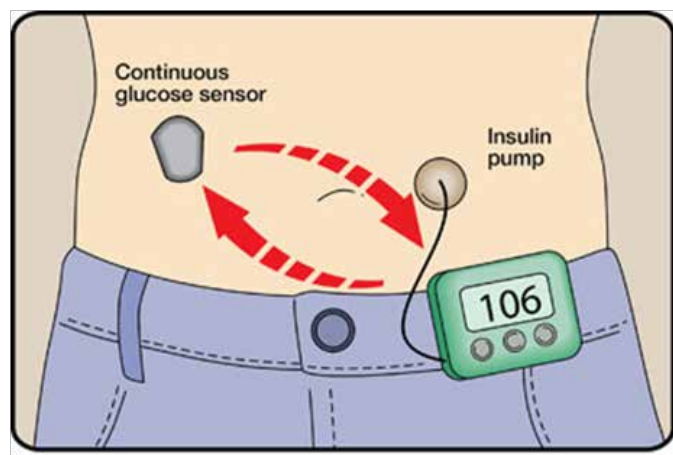
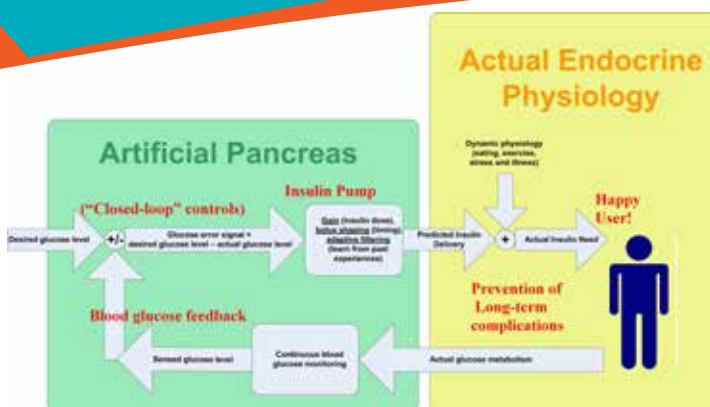
A small pilot study showed that, during a short hospital stay mainly for foot-ulcer complications, glucose levels of patients with type 2 diabetes who were on insulin were better managed by a closed-loop insulin-delivery system (artificial pancreas) than by subcutaneous insulin injections. Compared with 20 patients who received standard care, 20 patients who received a fixed insulin dose, via the automated closed-loop delivery system had glucose levels that were more often within the recommended target range during their hospital stay, with no adverse effects.

The insulin-only hybrid closed-loop 670G system (Medtronic MiniMed) is the furthest along in development and its premarket approval submission with the US Food and Drug Administration is anticipated this summer. If things go according to the plan, the first Artificial pancreas will hit the market by the end of 2016.

Reference: [www.medscape.com/viewarticle/865143#vp\\_2](http://www.medscape.com/viewarticle/865143#vp_2)



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# TODAY'S MUST WATCH

The following are few important drugs approved by US FDA during the month APRIL - JUNE 2016.

| BRAND              | DRUG  | INDICATION  |
|--------------------|---|---|
| Byvalson           | Nebivolol and Valsartan                               | Hypertension  |
| Afstyla            | Antihemophilic Factor                                 | Treatment of hemophilia A   |
| Nuplazid           | Pimavanserin  | Treatment of hallucinations and delusions associated with Parkinson's disease |
| Bevespi Aerosphere | Glycopyrrolate and Formoterol fumarate                | Treatment of chronic obstructive pulmonary disease                            |
| Descovy            | Emtricitabine and Tenofovir alafenamide               | Treatment of HIV-1 infection  |
| Odefsey            | Emtricitabine, Rilpivirine, and Tenofovir alafenamide | Treatment of HIV-1 infection  |
| Ocaliva            | Obeticholic acid                                      | Treatment of primary biliary cholangitis                                      |

**Pimavanserin:** Parkinson's disease (PD) treatment is frequently complicated by the presence of psychotic symptoms, most prominently hallucinations and delusions. It is a selective inverse agonist of the 5-hydroxytryptamine 2A (5-HT<sub>2A</sub>) receptor intended to treat patients with Parkinson's disease psychosis (PDP). It is the first FDA approved medication for the treatment of PDP. Its antipsychotic effects coupled with its lack of motor side effects could make it an ideal drug for treating psychotic symptoms in PD.

**Reference:** [www.ncbi.nlm.nih.gov/pubmed/24016069](http://www.ncbi.nlm.nih.gov/pubmed/24016069)

**Descovy:** Is a two-drug combination of emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV nucleoside analog reverse transcriptase inhibitors. It is specifically indicated in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. It comes with a black box warning of lactic acidosis and severe hepatomegaly with steatosis.

**Reference:** [www.centerwatch.com/drug-information/fda-approved-drugs/drug/100139/descovy](http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100139/descovy)

# STUDENTS CORNER

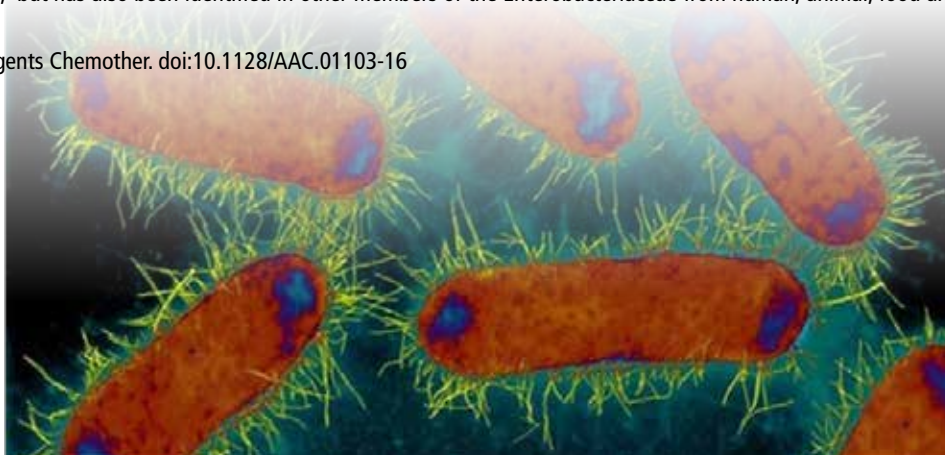
## *E coli* Resistant to COLISTIN

Researchers have spotted the first known instance of bacteria impervious to the last-resort antibiotic colistin in the United States, exacerbating fears of super bugs that can turn an ordinary infection deadly.

The case involves a 49-year-old woman treated at a clinic for a urinary tract infection, whose urine culture revealed a strain of *Escherichia coli* that was later found to be resistant to colistin. The *E coli* strain was isolated and was included in the first 6 ESBL(Extended Spectrum Beta Lactamase) -producing *E.coli* selected for colistin susceptibility testing, and it was the only isolate to have a MIC of colistin of 4µg/ml (all others had MICs ≤0.25 µ/ml).

This recent discovery of a plasmid-borne colistin resistance gene, *mcr-1*, heralds the emergence of truly pan-drug resistant bacteria. The gene has been found primarily in *Escherichia coli*, but has also been identified in other members of the Enterobacteriaceae from human, animal, food and environmental samples on every continent.

**Reference:** Antimicrob. Agents Chemother. doi:10.1128/AAC.01103-16



# CLINICAL CONNECTION

## Drug safety communication: Olanzapine

- ▶ FDA is warning that the antipsychotic medicine Olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. FDA is adding a new warning to the drug labels for all Olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- ▶ DRESS may start as a rash that can spread to all parts of the body. It can include fever and swollen lymph nodes and a swollen face. It causes a higher-than-normal number of infection-fighting white blood cells called eosinophils that can cause inflammation, or swelling. DRESS can result in injury to organs including the liver, kidneys, lungs, heart, or pancreas, and can lead to death. DRESS is a potentially fatal drug reaction with a mortality rate of up to 10%.

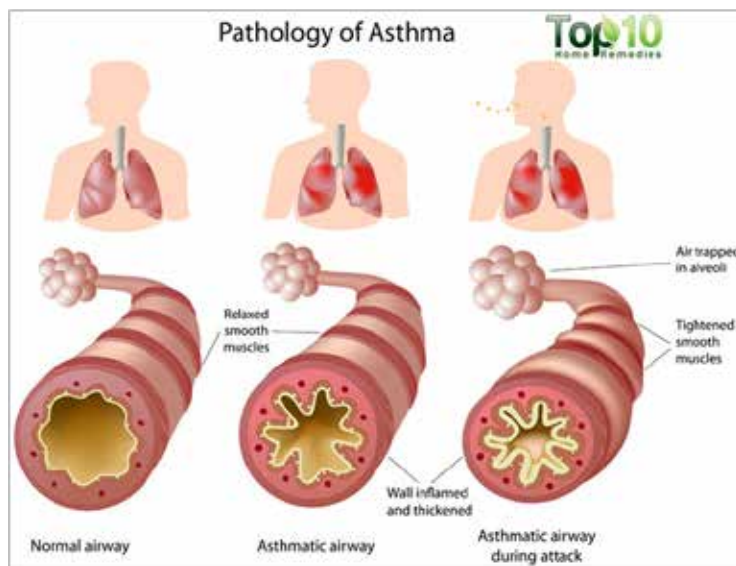
**Reference :** [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm500123](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm500123)

## Drug safety communication: Off-Label Ketoconazole

- ▶ The US Food and Drug Administration (FDA) is warning clinicians against the off-label prescribing of ketoconazole tablets to treat skin and nail fungal infections because the risk for serious liver damage and death outweighs the benefits.
- ▶ In July 2013, the FDA removed skin and nail fungal infections as indications for ketoconazole tablets in light of possible adverse events, which also include adrenal gland problems and harmful interactions with other drugs. Ketoconazole should be reserved to treat serious fungal infections when no other antifungal therapies were found to be effective.
- ▶ However, clinicians have continued to prescribe ketoconazole tablets for skin and nail fungal infections despite the label change.
- ▶ The FDA has received one report of a fatality related to oral ketoconazole since July 2013. The patient died of liver failure after taking the tablets for infected nails.

**Reference :** <http://www.fda.gov/Drugs/DrugSafety/ucm500597.htm>

# ADVICE



## 3<sup>rd</sup> MAY : WORLD ASTHMA DAY

- Asthma is a chronic inflammatory disease which involves airway inflammation, intermittent airflow obstruction and bronchial hyper-responsiveness.
- The onset of Asthma for most patients being early in life and is progressive. The treatment with anti-inflammatory therapy does not appear to prevent progression of underlying disease severity.
- Bronchodilators and Corticosteroids are the main line of therapy given in inhalation form to prevent the progression of the disease and its symptomatic management.



## Asthma symptoms



# STAFF PUBLICATIONS

1. S. Vidyadhara, R.L.C Sasidhar, B. Venkateswara Rao, T.Sai Babu and D.Lakshmi Harika Stability-Indicating High Performance Liquid Chromatographic Method For the Determination of Nelarabine. Oriental Journal of Chemistry. Vol. 32(1), 601-607 2016.
2. Vidyadhara. S, Sasidhar RLC, Chowdary Y.A, Lavanya K.L, and Lakshmi S.B. Design and Evaluation of Rosuvastatin SMEDDS For Enhancing Solubility and Dissolution Rate. INDIAN DRUGS. 53 (03), March 2016.
3. Arun Kumar.C, Vidyadhara.S, Sasidhar.RLC. Evaluation of anti-cataract activity of methanolic Extract of ziziphus xylopyrus fruit using in-vitro model on goat lens and chick lens. Pharmacology Online. 2015, vol.3, 91-97.
4. B. Nagaraju, S. Vidyadhara, Ch. Aruna Kumar, S. Vikas, and D.Suryanarayana Raju. Evaluation of cardioprotective activity of Ethanolic extract of dried leaves of Cinnamomum tamala in rats. International Journal of Biomedical and Advance Research. 2016; 7(4): 181-186.
5. B. Nagaraju, S. Vidyadhara, Ch. Aruna Kumar, D. Suryanarayana Raju, S. Vikas and S. Siva Prasad. Evaluation of antiulcer and thrombolytic activity of aqueous extract of Tiliacora acuminata bark in albino wistar rats. Journal of Chemical and Pharmaceutical Research, 2016, 8(4):973-979.
6. S.Vidyadhara, A. Ramu, D. Sandeep, R. L.C. Sasidhar and S. Vikas. Evaluation of anti-inflammatory, analgesic and immunosuppressant activities of aceclofenac solid dispersions on wistar rats. Der Pharmacia Lettre, 2016, 8 (8):100-107.
7. G.Priyadrsrshini, S.Vidyadhara, D.Jaswant ram, TNV.Ganesh Kumar. Synthesis of Iodo derivative of lamivudine and UV spectroscopic method development for its determination. Inventi Rapid: Pharm Analysis & quality Assurance, Issue 3, Vol 2016.

## Graduation Day Celebrations at CHIPS (02-04-2016)



## Felicitation of Dr. K. Basavapurnaiah on the occasion of being nominated as ANU EC Member (02-04-2016)



## IPA AP State Branch Induction (18-06-2016)



## International Yoga Day Celebration at CHIPS (21-06-2016)



## Prof. G. Diwakar, Editor IJPS and Prof. Kalyani Prakasam, Co-ordinator, POWER-India at CHIPS (21-06-2016)



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