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Technivie®: A New Formulation for 'Hepatitis C'

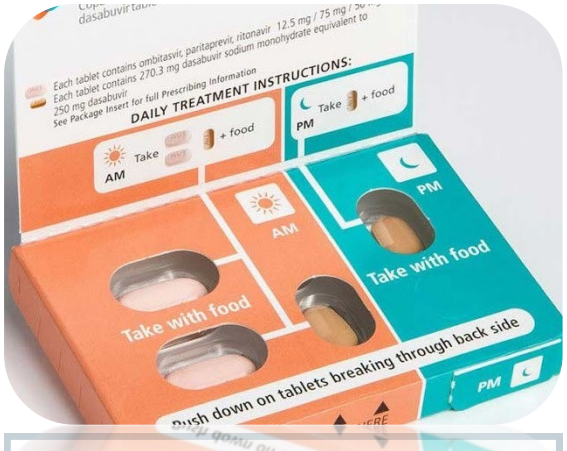
By: Karim Edward

In July 2015, Technivie® was granted the U.S. Food and Drug Administration (FDA) approval for the treatment of chronic hepatitis C genotype 4 in infected patients without scarring and poor liver function, such as that found in liver cirrhosis.

Technivie® combined with Ribavirin is the first regimen which has demonstrated safety and efficacy for the treatment of chronic hepatitis C genotype 4 infections without administering interferon which gives rise to significant adverse effects.(1)

The Technivie® formulation tablet contains Ombitasvir 12.5mg/Partaprevir 75mg/ ritonavir 50mg; Ombitasvir inhibits HCV NS5A, and interferes with viral RNA replication and virion assembly. Paritaprevir inhibits HCV NS3/4A protease and interferes with HCV coded polyprotein cleavage necessary for viral replication. Ritonavir is not active against HCV. Ritonavir is a potent CYP3A inhibitor, which increases peak and trough plasma-drug concentrations of paritaprevir and overall drug exposure, thus increasing the area under the curve (AUC). (2)

The American Association for the Study of Liver Disease (AASLD) guidelines recommends a daily fixed-dose of paritaprevir (150 mg)/ritonavir (100 mg)/ombitasvir (25mg) in combination with weight-based ribavirin for 12 weeks for the treatment of genotype 4 treatment-naïve patients without cirrhosis or with compensated cirrhosis in order to achieve a sustained virologic response. (3)



Technivie® combined with Ribavirin is the first regimen which has demonstrated safety and efficacy for the treatment of chronic hepatitis C.

Technivie® is available in the form of tablets, the dose is two tablets once daily every morning for 12 weeks and taken with food.(2) The FDA warns of elevated liver enzymes in patients taking Technivie® especially in female patients taking ethinyl estradiol oral contraceptives (1). There are no dose adjustments required for renaly impaired patients or patients with mild hepatic impairment (Child-Pugh class A). (2)

References:
1. *"FDA Approves Technivie for Treatment of Chronic Hepatitis C Genotype 4." FDA. 24 July 2015. 13 Dec 2016.*
2. *"Lexicomp Online." Lexicomp. Dec 2016. 13 Dec 2016.*
3. *"AASLD/IDSA. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C". 27 Sep. 2016. 13 Dec 2016.*

Rosiglitazone is No Longer Restricted

By: Abdel-Rahman Gamal

Finally, the Food and Drug Administration (FDA) is eliminating the risk evaluation and mitigation strategy (REMS) for rosiglitazone-containing diabetes medicines which indicates that high risk of heart attack does no longer exist. (1)

In 2007, a meta-analysis of clinical study data, published in the New England Journal of Medicine, reported that rosiglitazone approved as Avandia® carried a significant risk of heart attack. Therefore; the FDA declared that rosiglitazone had to be prescribed as the last resort drug and REMS had to be used. (2)

In 2013, a removal of some prescribing and dispensing restrictions for rosiglitazone was required by the FDA because data did not demonstrate an increased risk of heart attack with rosiglitazone compared to metformin and sulfonylurea.(1)

The FDA has continued monitoring rosiglitazone-containing medicines and found no new patient safety information. As a result, FDA has determined that REMS is no longer necessary to make sure that the benefits of rosiglitazone outweigh its risks. (1)

References

1. *"FDA Drug Safety Communication: FDA Eliminates the Risk Evaluation and Mitigation Strategy (REMS) for Rosiglitazone-containing Diabetes Medicines." FDA U.S. Food & Drug Administration. FDA U.S. Food & Drug Administration, 16 Dec. 2015. Web. 21 Dec. 2016*
2. *"FDA Eliminates Risk Plan for Avandia Diabetes Drugs; Risks Don't Outweigh Benefits." lexis legal news. 17 Dec. 2015. Web. 21 Dec. 2016.*

"Avandia® Has No Significant Risk of Heart Attack."

Adjuvanted Fluad® Approved for Seasonal Influenza

By Eman Tarek

"90% of Seasonal Influenza-Related Deaths Was Among 65 Years and Older."

The U.S. Food and Drug Administration (FDA) approved Fluad®, to be the first seasonal influenza vaccine to contain an adjuvant, formulated to improve the immune response for people 65 years of age and older. (1)

According to the Centers for Disease Control and Prevention, in the previous years, it is estimated that 80 to 90 percent of seasonal influenza-related deaths and 50 to 70 percent of seasonal influenza-related hospitalizations have occurred among people 65 years of age and older. (1)

Fluad® is a trivalent vaccine designed to protect against two subtypes of influenza A virus and one of influenza B virus(1) manufactured using an egg-based process, formulated with oil-in-water mixture adjuvant called MF59. (1)

The adjuvant added is intended for ameliorating the immune response of older individuals to the vaccine; since some persons of 65 years of age and over may not respond well to influenza vaccine as younger individuals. (2)

Flaud® is not to be given to anyone with a history of severe allergic reaction to any component of the vaccine, including egg protein (3), if Guillain - Barré syndrome (GBS) has occurred within 6 weeks of receiving prior influenza vaccine, the decision to give Fluad® should be based on careful consideration of the benefits and risks.(3)

References:

1. *"FDA Approves First Seasonal Influenza Vaccine Containing an Adjuvant." FDA. 24 Nov. 2015. Web. 17 Apr. 2016.*
2. *"Trivalent Inactivated Influenza Vaccine – Adjuvanted (Fluad®): For Individuals 65 Years of Age and Older Living in Long-term Care Homes." 2015. Web. 17 Apr. 2016.*
3. *FLUAD™ [package insert]. Novartis Vaccines and Diagnostics, Inc.; Nov. 2015.*

Adjuvant improves immune response of elderly people.

FDA Clears a New Device for Insomnia

By Sherif Tahoon

The U.S. Food and Drug Administration (FDA) has granted commercial clearance for the Cerêve™ Sleep System, a device that reduces latency to sleep for people with insomnia.(1)

Sleeping pills have by far been the most common medical treatment but this comes with well-established safety risks, including decreased mental alertness the morning after use. (2)

The Cerêve Sleep System is a prescription device that helps reduce latency to stage 1 and stage 2 sleep by keeping the forehead cool.(2)

The inspiration behind the new device came from functional brain imaging studies conducted by Eric Nofzinger, MD, a board-certified sleep physician and founder of Cerêve, at the University of Pittsburgh in Pennsylvania, the company notes in a press release. (2) These studies confirmed that the frontal cortex, or executive brain, stays active in people with insomnia during sleep, preventing them from getting deeper, more restorative sleep.(1)

Dr Nofzinger found that gently cooling the forehead within a precise, clinically proven therapeutic range reduced this activity in the frontal cortex. The new software-controlled bedside device cools and pumps fluid to a forehead pad that is worn throughout the night.(2) Clinical subjects found the device easy to use and to wear, and commented that it was a calming and comfortable experience.(1)

The Cerêve System offers a clinically proven and safe alternative to pills, with the potential to help millions get to sleep fast. (2)

References:

1. *Pa., Oakmont. "FDA Clears Cerêve Device for Treating Insomnia Patients by Helping Them Get to Sleep Faster." Venturebeat. N.p., 6 June 2016. Web. 14 June 2016.*
2. *Pauline, Anderson. "FDA Approves New Device for Insomnia." Medscape. N.p., 8 June 2016. Web. 14 June 2016.*

Cerêve

A new Device for people with insomnia

"Cerêve™: easy to use, easy to wear, and a calming, comfortable experience."

DAPT Recommendations for Long Term Use of Plavix®

By Merna Ashraf

FDA MedWatch announced that using clopidogrel with aspirin for more than one year does not affect either the risk of overall deaths in patients with or at risk of Coronary Heart Disease (CHD) or even the risk of cancer deaths or of developing cancer. (1)

The previous information was supported by Dual Anti-Platelet Therapy trial (DAPT) and other large, long-term clinical trials of clopidogrel with data available on rates of death, death from cancer, or cancer reported as an adverse event. Results from the DAPT trial were published in the New England Journal of Medicine in November 2014. (2)

The results from meta analyses indicated that long-term (12 months or longer) dual antiplatelet therapy with clopidogrel and aspirin do not appear to change overall risk of death when compared to short-term (6 months or less) clopidogrel and aspirin, or aspirin alone. Also, there was no apparent increase in risks of cancer-related deaths or cancer-related adverse events with long-term treatment. (3)

FDA MedWatch reported that it's working with the manufacturers to update clopidogrel labels with these results.(1) Yet, patients should not stop taking any antiplatelet medications including clopidogrel without discussion with the health care professional to avoid risk of heart attacks and blood clots. (2)

References

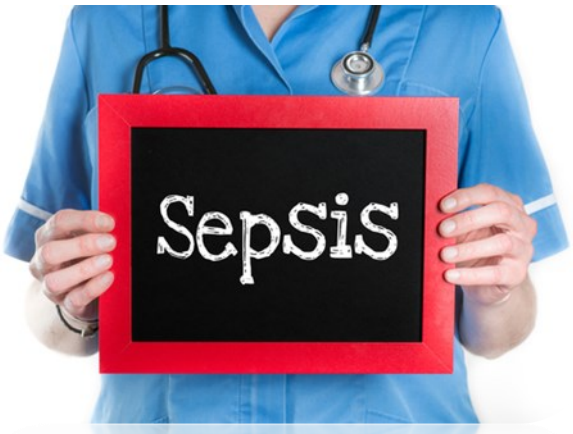
1. *"FDA: No Raised Mortality, Cancer Risk with Long-Term Clopidogrel." Medscape. Ed. Deborah Brauser. N.p., 6 Nov. 2015. Web.*
2. *"FDA Drug Safety Communication: FDA Review Finds Long-term Treatment with Blood-thinning Medicine Plavix (clopidogrel) Does Not Change Risk of Death." FDA, 9 Dec. 2015. Web.*
3. *" Plavix (clopidogrel): Drug Safety Communication - Long-term Treatment Does Not Change Risk of Death. FDA, 16 Nov. 2015. Web.*

New Criteria for Sepsis and Septic Shock for the First Time in 15 Years

BY: Sherif Tahoon

"New Definitions of Sepsis and Septic Shock Published by the European Society of Intensive Care Medicine and Society of Critical Care Medicine."

The definitions of sepsis and septic shock have been updated for the first time in 15 years. New criteria for septic shock have been added and standards for the rapid recognition of sepsis related organ failure have been simplified to find patients faster and get treatment started right away.[1]



The much anticipated new definitions of sepsis and septic shock have been published by the European Society of Intensive Care Medicine and Society of Critical Care Medicine. [2]

For more than 2 decades, the cornerstone of sepsis identification included potential infection and presence of two of four systemic inflammatory response syndrome (SIRS) criteria.[2] In the new criteria, the quick sepsis related organ failure assessment (quickSOFA, or qSOFA) score is used to assess just three symptoms in patients with suspected sepsis: [1,3]

1. An alteration in mental status
2. A decrease in systolic blood pressure of less than 100 mmHg
3. A respiration rate greater than 22 breaths/min [3]

If patients with infection show two of the three criteria, they should be considered likely to be septic. [1] It can be done quickly and without the use of a blood test.[3]

On the other hand, if a patient has two or three components of qSOFA, the patient should be examined for organ failure. Septic shock differs from sepsis in that the complications are more severe and the risk of patient death is greater. The task force has identified two new clinical criteria that clinicians should use in diagnosing patients with septic shock. These include: [3]

- Persisting hypotension requiring vasopressors to maintain MAP ≥65 mm Hg
- Blood lactate >2 mmol/L despite adequate volume resuscitation

These recommendations not only advance new definitions, but also offer clinical guidance to quickly identify patients with or at risk of developing sepsis.[3]

References:

1. *"New Criteria Released for Defining Sepsis, Septic Shock." Medscape. 23 Feb. 2016. Web. 16 Mar. 2016.*
2. *"Assessing New Clinical Criteria for Septic Shock." NEJM Journal Watch. 23 Feb. 2016. Web. 16 Mar. 2016.*
3. *"Sepsis Definitions: New Recommendations Aim to Redefine Definition and Enhance Diagnosis of Sepsis, Septic Shock." Society of Critical Care*

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