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FDA Greenlights Qtern® for Treatment of Type 2 Diabetes

By: Mina Adel



On February 2017, The US Food and Drug Administration (FDA) has approved once-daily Qtern® for the treatment of type 2 diabetes. ⁽¹⁾

This new combination (10mg dapagliflozin and 5mg saxagliptin) is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type-2 diabetes who have inadequate control with dapagliflozin (10mg) or who are already treated with dapagliflozin and saxagliptin. ⁽²⁾

Earlier that month, the Egyptian Ministry of Health approved and launched the SGLT-2 inhibitor Forxiga® (dapagliflozin). ⁽³⁾

Forxiga® demonstrated significant reductions in HbA1c and has also been shown to reduce weight and blood pressure. ⁽²⁾

Qtern® combines two anti-hyperglycaemic agents with complementary mechanisms of action. ^(1,4)

(1) Saxagliptin, through the selective inhibition of dipeptidyl peptidase-4 (DPP-4), enhances glucose-mediated insulin secretion (incretin effect).

(2) Dapagliflozin, a selective inhibitor of sodium-glucose co-transporter 2 (SGLT2), inhibits renal glucose reabsorption independently of insulin.

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1. "Drugs@FDA: FDA Approved Drug Products." *Accessdata.fda.gov*. N.p., 27 Feb. 2017. Web.
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3. "A New Drug for Management of Diabetes through Kidneys." *Almasryalyoum.com*. N.p., 10 Feb. 2017. Web.
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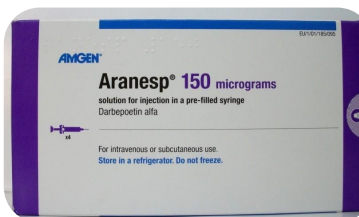


Health Canada: Risk of Severe Reactions with Aranesp®

By: Sherif Tahoón

Health Canada has released a warning message on May 2017 concerning Aranesp® severe skin reactions and is currently working to include this safety information in the Product Monograph. ⁽¹⁾

Aranesp® (darbepoetin alfa) is a prescription medicine used in management of anemia associated with chronic kidney disease (kidney failure) or anemia associated with chemotherapy administration in cancer patients. ⁽²⁾



Severe blistering, mucosal ulceration, and exfoliation cutaneous reactions, including life-threatening Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) have been reported in patients treated with Aranesp® in the post-marketing setting. ⁽¹⁾

SJS/TEN are serious life-threatening conditions that often begin with flu-like symptoms including fever, tiredness, muscle and

joint pain which are followed by a widespread rash with reddening and blistering of the skin and moist lining of the mouth, eyes, nose, throat, or genital area. This often leads to peeling and shedding of the affected skin which looks like a severe burn. ⁽¹⁾

Patients should be advised to stop using Aranesp® in case of having a serious allergic reaction, and get medical help right away. ⁽²⁾

Healthcare professionals are reminded to discontinue Aranesp® therapy immediately if a severe skin reaction occurs or SJS/TEN is suspected or permanently discontinue Aranesp® if SJS/TEN is confirmed. ⁽¹⁾

References:

1. "ARANESP - Risk of Severe Skin Reactions: Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis." Healthcanadians.gc.ca. N.p., 5 May 2017. Web. 8 June 2017.
2. "Aranesp." Aranesp.com. N.p., n.d. Web. 8 June 2017.



HEALTH CANADA:
"Stop Using
Aranesp® in Case
of Serious Allergic
Reaction"

"RRMS Trial Showed 46% Drop in Annual Relapse Rates"

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1. "FDA Approves New Drug to Treat Multiple Sclerosis." U.S. Food and Drug Administration Home Page. N.p., 29 Mar. 2017. Web. 1 Apr. 2017.
2. Anderson L. "Multiple Sclerosis: What's New in MS Treatment Options?" DRUGS. N.p., 26 Jan. 2017. Web. 1 Apr. 2017.
3. Jennifer Clopton. "New MS Drug Approved by FDA." WebMD. N.p., 29 Mar. 2017. Web. 1 Apr. 2017.
4. Basel. "FDA Approves Roche's OCREVUS™ (ocrelizumab) for Relapsing and Primary Progressive Forms of Multiple Sclerosis." Roche. N.p., 29 Mar. 2017. Web. 1 Apr. 2017.



"Ocrelizumab" a Breakthrough in MS Treatment

By: Rania Zakaria

On March 2017, Ocrevus® (Ocrelizumab) was approved by the U.S. Food and Drug Administration (FDA) for treatment of primary progressive (PPMS) and relapsing form of Multiple Sclerosis (MS). ⁽¹⁾

Ocrevus® is the first drug to be approved for PPMS and the only drug available for this indication. ⁽¹⁾

Ocrevus® is a humanized monoclonal antibody designed to selectively target CD20-positive B cells ⁽²⁾, while most treatments of MS only Target T-Cells.

In clinical trials, Ocrevus® helped to slow the progression of PPMS by 24%, compared with a placebo. ⁽³⁾

The relapsing-remitting MS (RRMS) trial showed a 46% drop in annual relapse rates, compared with an existing and commonly used MS drug, interferon beta-1a (Rebif). ⁽³⁾ 48% of patients in

the RRMS trial had no relapses, no worsening of neurological symptoms, and no new brain lesions seen on MRI scans. ⁽³⁾

Ocrevus® dosage regimen is convenient for non-compliant patients; it is a 600mg Intravenous drug to be administered every 6 months. ⁽⁴⁾

Most common side effects associated with Ocrevus® were infusion reactions and upper respiratory tract infections. ⁽⁴⁾

Ocrevus® should not be used in patients with hepatitis B infection or a history of life-threatening infusion-related reactions and it may increase the risk for malignancies, particularly breast cancer. ⁽¹⁾ Not only is Ocrevus® another treatment option

for relapsing remitting MS, but it's also a new hope for a better future in PPMS.





Parasabiv®: Approved for Secondary HPT in Patients on Dialysis

By: Nourhan Mohamed

On February 2017, the U.S. Food and Drug Administration (FDA) has approved Parasabiv® (etelcalcetide) for the treatment of secondary hyperparathyroidism (HPT) in adult patients on hemodialysis. ⁽¹⁾

Secondary hyperparathyroidism is a serious chronic condition, which affects people receiving dialysis. It refers to excessive secretion of parathyroid hormone (PTH) by parathyroid glands in response to decreased renal function and impaired mineral metabolism. The elevated levels of PTH can lead to an increase in the release of calcium and phosphate from the bones. ⁽¹⁾

This calcimimetic agent works by modulating the calcium-sensing receptor (CaSR), and enhancing its activation by extracellular calcium. PTH secretion is decreased by the activation of CaSR on parathyroid chief cells. ⁽²⁾

"The First Therapy Approved for This Condition in 12 Years"



The novel calcimimetic, "Parasabiv®", is the first therapy approved for this condition in 12 years and the only calcimimetic that can be administered intravenously three times a week at the end of the hemodialysis session to effectively reduce levels of PTH, corrected calcium and phosphate. ⁽¹⁾

"The ability to provide my patients with an intravenous calcimimetic and help ensure they receive the therapy they need is a tremendous milestone in the management of this frequently undertreated chronic progressive disease," said by Geoffrey A. Block, M.D., nephrologist at Denver Nephrologists describing this newly approved drug by FDA. ⁽¹⁾

References :-

1. "FDA Approves Parasabiv." *Drugs.com*. N.p., Feb. 2017. Web.
2. "Parasabiv (etelcalcetide)." *Centerwatch*. N.p., Feb. 2017. Web.



Kevzara® a New Hope for DMARDs Non-Responders

By: Sherif Tahoon

On May 2017, the US Food and Drug Administration (FDA) approved sarilumab (Kevzara®) for treatment of rheumatoid arthritis (RA), not responding well to disease-modifying antirheumatic drugs (DMARDs). ⁽¹⁾

Late last year, sarilumab approval was declined because of manufacturing problems at a Sanofi plant in France. At that time, Sanofi assumed it was working on the problems. ⁽¹⁾

Sanofi and Regeneron Pharmaceuticals has now gained its approval for the treatment of adult patients with moderately to severely active RA, who have had an inadequate response or intolerance to one or more DMARDs, such as methotrexate (MX). ⁽²⁾

tion, which can be self-administered. ⁽²⁾



Sarilumab is a monoclonal antibody that binds to the interleukin-6 receptor, a cytokine associated with inflammation. ⁽¹⁾ This treatment can be used as monotherapy or in combination with MX or other DMARDs. ⁽²⁾

Patients are recommended to take 200 mg once every 2 weeks given as a subcutaneous injection.

The dose can be reduced to 150 mg once every 2 weeks to help manage complications of neutropenia, thrombocytopenia, and elevated liver enzyme levels. ⁽¹⁾

Kevzara® approval is based on 2, phase 3 trials involving 2900 adult patients that demonstrated statistically significant, clinically meaningful improvements in patients being treated with Kevzara® plus background DMARDs. ⁽²⁾

References:

1. Frellick, Marcia. "FDA Approves Sarilumab for Adults with Rheumatoid Arthritis." *Medscape*. N.p., 23 May 2017. Web. 9 June 2017.
2. "Rheumatoid Arthritis Drug Wins FDA Approval." *Pharmacy Times*. N.p., 22 May 2017. Web. 23 May 2017.



Tramadol and Codeine –New Contraindications and Warnings

By: Abdel-Rahman Gamal

The US Food and Drug Administration (FDA) is restricting codeine and tramadol medicines use in children and Breastfeeding women. ⁽¹⁾

Warnings were previously issued by the FDA concerning the use of tramadol and codeine in children due to the risk of serious breathing problems and death. ⁽²⁾

As a result, FDA is requiring several changes to the labels of these drugs. FDA is now adding:

- FDA's strongest warning, called a Contraindication, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years. ⁽¹⁾
- A new Contraindication to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. ⁽¹⁾
- A new Warning to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems. ⁽¹⁾
- A strengthened Warning to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can

include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death. ⁽¹⁾

In case the use of tramadol or codeine is deemed necessary in a pediatric patient, caregivers should be advised to monitor closely for signs of shallow or difficult breathing, confusion, or oversedation. ⁽²⁾

“Beware of Giving Kids Codeine or Tramadol”



References

1. "Codeine and Tramadol Medicines: Drug Safety Communication - Restricting Use in Children, Recommending Against Use in Breastfeeding Women." FDA.gov. N.p., 20 Apr. 2017. Web. 8 June 2017.
2. "Tramadol and Codeine –New Contraindications and Warnings Regarding Risk of Serious Breathing Problems and Death in Pediatric Patients - UPDATED." Pharmacyservices.utah.edu. N.p., 9 May 2017. Web. 8 June 2017.



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