June

Better Pharmacist Knowledge

Jordan Drug Information and Toxicology Center 2021

2021

Second course of IVIG not beneficial for patients with severe Guillain-Barré syndrome(April 2021):

For patients with Guillain-Barré syndrome treated initially with IVIG **who show further deterioration or no improvement**, we suggest against retreating with IVIG because it exposes patients to adverse risks without additional benefit (Grade 2C).

For patients with severe Guillain-Barré syndrome (GBS) whose symptoms worsens or fails to improve after a course of intravenous immune globulin (IVIG), a repeat course has sometimes been given, despite uncertain benefit.

In a randomized trial of 93 patients with GBS and a poor predicted outcome, those assigned to a second course of IVIG (given two to four days after completion of the first course) had similar disability but more adverse effects, including thromboembolic complications, than those who were assigned to placebo. **Based on these data, we suggest against retreating with a second course of IVIG for patients with GBS**. [1]

Fluoroquinolone antibiotics: new restrictions and precautions for use due to very rare reports of disabling and potentially long-lasting or irreversible side effects

Disabling, long-lasting or potentially irreversible adverse reactions affecting musculoskeletal and nervous systems have been reported very rarely with fluoroquinoloneantibiotics. Fluoroquinolone treatment should be discontinued at the first signs of a serious adverse reaction, including **tendon pain or inflammation**.[2]

Parenteral nutrition products for neonates and children below 2 years of age – Protect from light until administration is completed

When PN products containing amino acids and/or lipids are used in neonates and children below 2 years of age, the solution (containers and administration sets) **should be protected from light exposure until administration is completed.** [3]

Domperidone for nausea and vomiting: lack of efficacy in children - Drug Safety Alert

Domperidone is **no longer licensed for use in children younger than 12 years or those weighing less than 35 kg.** Results from a placebo-controlled study in children younger than 12 years with acute gastroenteritis did not show any difference in efficacy at relieving nausea and vomiting compared with placebo.

Change of indication:

Domperidone is now authorised for the relief of symptoms of nausea and vomiting **only in adults and adolescents 12 years of age or older and weighing 35 kg or more.**

Consider alternative treatments to domperidone in children younger than 12 years of age who need relief of symptoms of nausea and vomiting. [4]

Rivaroxaban (Xarelto®): Reminder that 15 mg and 20 mg tablets should be taken with food

MHRA has received a small number of reports suggesting lack of efficacy (thromboembolic events) in patients taking 15 mg or 20 mg rivaroxaban on an empty stomach; remind patients to take 15 mg or 20 mg **rivaroxaban tablets with food**.[5]

Tramadol Contraindication in children

Medsafe has informed health-care professionals of updated advice on the use of tramadol in children. Tramadol is centrally-acting synthetic analgesic, used to relieve moderate to severe pain when paracetamol or nonsteroidal anti-inflammatory drug (NSAID) is not adequate. Tramadol is metabolized by CYP2D6 to yield principal active metabolite. Patients with a deficiency of CYP2D6 may have reduced benefit from tramadol, whereas patients who are ultra-rapid metabolizers may be more sensitive to adverse drug reactions (ADRs).

Following review of their safety data, the companies have now **contraindicated the use of tramadol in children aged under 12 years, as well as in children under 18 years for post-operative pain management.**

The CARM has received 83 ADRs relating to tramadol from 2015 to 2019, where the most frequent ADRs were rash, vomiting, and nausea. Serotonin syndrome and convulsions were also reported in five cases for each. [6]

References:

1. Second course of IVIG not beneficial for patients with severe Guillain-Barré syndrome; Practice Changing UpToDate.
2. Fluoroquinolone long lasting or irreversible side effects. UpToDate.
3. Parenteral Nutrition From Light Improves Survival Rate in Premature Infants. JPEN
4. Domperidone for nausea and vomiting: lack of efficacy in children.gov.uk
5. Xarelto® taken with food. UpToDate.
6. Tramadol contraindication in children.Medsafe.govt.nz

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Levothyroxine – Close monitoring recommended in the event of a brand change

Advice to Healthcare Professionals

- Levothyroxine-containing products **should not be used interchangeably,** and should be prescribed and dispensed by brand name.
- Patients on established levothyroxine treatment who are changed to a different brand or pharmaceutical form (i.e. tablets to oral solution) **should be closely monitored clinically and have thyroid function tests** performed during the transition period due to a potential risk of thyroid imbalance. In some patients, a dose adjustment may be necessary.
- Patients should be informed of any changes in the brand of levothyroxine prescribed or dispensed and therefore of the requirement for close monitoring should a change become necessary.
- Patients should be made aware of the symptoms of thyroid imbalance and should be encouraged to consult their physician in the event that they experience any of these symptoms.[6]

PPIs and Clopidogrel:

Treatment decisions regarding concomitant use of clopidogrel and PPIs must balance the overall risks and benefits and consider the risk of cardiovascular and gastrointestinal complications in individual patients. In some patients the benefits of PPI may outweigh the risk of reduced clopidogrel efficacy.

The FDA, MHRA and EMA currently advise avoiding omeprazole and esomeprazole in patients taking clopidogrel.

There is insufficient evidence available regarding which PPI is least likely to interact, however based on data from pharmacokinetic and pharmacodynamic studies and the small amount of data available from the COGENT study, the **FDA suggest that pantoprazole is the least likely to interact.**

Stockley's Drug interactions suggests that **pantoprazole is the least likely to interact with clopidogrel and also suggest lansoprazole and rabeprazole** as suitable alternatives.[7]

Montelukast – Reminder of risk of neuropsychiatric reactions and product information update

Montelukast is indicated for use in the prophylaxis and treatment of asthmatic conditions and neuropsychiatric reactions including nightmares, insomnia, somnambulism, anxiety, agitation aggressive behaviour or hostility, depression and psychomotor hyperactivity are known to occur, albeit, infrequently in association with its use. Healthcare professionals are advised to **be alert for the occurrence of neuropsychiatric reactions** occurring amongst patients treated with Montelukast and to communicate this risk to patients and carers.The recently completed review considered cases of dysphemia which have been reported in association with montelukast. **The majority of these cases involved the paediatric population, especially young children less than five years of age**. Based on review of this data, an association between montelukast and dysphemia as well as other closely related speech disorders cannot be excluded. [8]

Single-dose ceftriaxone for treatment of gonococcal infections (January 2021)

For suspected or confirmed uncomplicated urogenital or anorectal gonococcal infection, we suggest **Ceftriaxone** in a single 500 mg intramuscular dose rather than other regimens (**Grade 2C**). For individuals who weigh ≥150 kg, we give a 1 g dose.

In the United States, the Centers for Disease Control and Prevention updated its guidance on treatment of gonococcal infections to recommend **Ceftriaxone as the preferred regimen, given as a single intramuscular dose of 500 mg for individuals who weigh <150 kg or 1 g for individuals who weigh ≥150 kg.**

Previous recommendations were for combination therapy with a **lower dose of ceftriaxone plus azithromycin**.

However, the previous preference for combination therapy was based on a theoretical benefit, which is now outweighed by decreasing susceptibility to azithromycin in *Neisseria gonorrhoeae*. A higher dose of ceftriaxone is recommended because of concern that lower doses are unlikely to be effective against isolates with higher minimum inhibitory concentrations to ceftriaxone, which have increased in prevalence. Presumptive treatment of chlamydia with **doxycycline** is warranted if chlamydia coinfection has not been ruled out.[9]

References:

6. Levothyroxine-accessed online viawww.hpra.ie.
7. PPI and Clopidogrel.UpToDate.
8. Montelukast – Reminder of risk of neuropsychiatric product information update.HPRA drug safety newsletter.
9. Single-dose ceftriaxone for treatment of gonococcal infections ;Practice Changing -UpToDate

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