Drug Safety Update

Latest advice for medicines users

The monthly newsletter from the **Medicines and Healthcare products Regulatory Agency** and its independent advisor the **Commission on Human Medicines**

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Contents

The **Medicines and Healthcare products Regulatory Agency** is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

The **Commission on Human Medicines** gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.

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This month, a review of available studies has concluded that emergency contraceptives are suitable for all women, regardless of the woman's weight. Data on the relationship between increasing body weight or body mass index (BMI) and efficacy of emergency contraceptives was found to be inconclusive—see article A1.

We remind you that serious and fatal infusion reactions have occurred with ofatumumab▼ (Arzerra▼) and other anti-CD20 monoclonal antibodies. Always give premedication 30 minutes to 2 hours before each ofatumumab infusion as described in the summary of product characteristics. If a severe reaction occurs, interrupt ofatumumab infusion and treat the reaction—see article A2.

We have just launched our online oral anticoagulants learning module for health professionals. Responding to users' comments on previous MHRA medicines learning modules, this one is much more interactive and is presented on a brand new platform for tracking and organising learning—see article O1.

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Drug safety advice

A1 Levonorgestrel and ulipristal acetate remain suitable emergency contraceptives for all women, regardless of body weight or body mass index

Emergency contraceptives remain suitable for all women regardless of the woman's weight or body mass index (BMI). Emergency contraceptives should be used as soon as possible after unprotected sex or contraceptive failure to prevent unintended pregnancy

Further information
Further information to give to women
http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con444304.pdf

Patient information leaflet for Levonelle One Step ('over the counter' emergency contraceptive pill)
http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1405923093994.pdf

Letter sent to healthcare professionals in July 2014
https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102202

European Medicines Agency press release July 2014
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/07/news_detail_002145.jsp&mid=WC0b01ac058004d5c1

A European review of available studies on the relationship between increasing body weight or BMI and efficacy of emergency contraceptives considered the data to be inconclusive. The overall conclusion was that emergency contraceptives are suitable for all women regardless of body weight or body mass index.

We remind you that emergency contraceptives do not prevent pregnancy in every instance. They should not be used to replace a regular contraceptive method. Levonorgestrel containing emergency contraceptives (eg, Levonelle) work best if taken within 12 hours of unprotected sex or contraceptive failure but can prevent pregnancy if taken up to 72 hours afterwards. Ulipristal containing contraceptives (eg, EllaOne) can prevent pregnancy if taken up to 5 days after unprotected sex or contraceptive failure.

Advice for healthcare professionals:

Advice to give to women:

- Use an emergency contraceptive as soon as possible after unprotected sex or contraceptive failure regardless of your weight or BMI.
- Emergency contraceptives should not be used to replace a regular contraceptive method.
- If your period is late or you have irregular bleeding after using an emergency contraceptive, use a pregnancy test.
- Speak to your doctor, nurse, or pharmacist if you have any concerns about emergency contraceptives.

Article citation: Drug Safety Update volume 8 issue 1, August 2014: A1.

A2 Ofatumumab▼: reminder of risk of serious and fatal infusion reactions—always give premedication and monitor patients carefully

Serious and fatal infusion reactions have occurred with ofatumumab and other anti-CD20 monoclonal antibodies. We remind you to always give premedication before each ofatumumab infusion. If a severe reaction occurs, interrupt ofatumumab infusion and treat the reaction. Patients with a history of decreased pulmonary function are at high risk of pulmonary complications from severe reactions

Ofatumumab▼ (Arzerra▼) is indicated for the treatment of patients with chronic lymphocytic leukaemia refractory to fludarabine and alemtuzumab.

Infusion reactions have occurred with intravenous ofatumumab. A fatal infusion reaction has occurred during administration of the first dose of ofatumumab to a 71 year old man.

We remind you of the recommendations to reduce the risk of infusion reactions with ofatumumab:

Advice for healthcare professionals:

- Ofatumumab should only be given under the supervision of a physician experienced in the use of cancer therapy and where facilities to monitor and treat infusion reactions are available.
- Always give patients premedication 30 minutes to 2 hours before each ofatumumab infusion according to the protocol in the summary of product characteristics (see left).
- Despite premedication, infusion reactions may still occur.
- If an infusion reaction occurs, interrupt ofatumumab infusion immediately and treat the symptoms of the reaction.
- Patients with a history of decreased pulmonary function may be at a high risk of pulmonary complications from severe reactions. Monitor these patients closely during ofatumumab infusion.

Further information
Summaries of product characteristics
http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm

Letter sent to healthcare professionals in July 2014
http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/Monthlylistsofinformationforhealthcareprofessionalsonthesafetyofmedicines/CON439844

Related medicines
Infusion reactions have also occurred with other anti-CD20 monoclonal antibodies such as rituximab (MabThera) and obinutuzumab (Gazyvaro). Specific recommendations to reduce the risk of infusion reactions for each of these products, including the use of pre-medications, are in the summary of product characteristics for each product (see left).

Article citation: Drug Safety Update volume 8 issue 1, August 2014: A2.

Other information from the MHRA

O1 E-learning module on oral anticoagulants

Oral anticoagulants learning module
http://www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/Medicineslearningmodules/Oralanticoagulants/index.htm

We have just launched our online oral anticoagulants learning module for health professionals.

Responding to users' comments on previous MHRA medicines learning modules, this one is much more interactive and is presented on a brand-new platform for tracking and organising learning.

The oral anticoagulants module outlines the key risks of these valuable and widely prescribed medicines. Designed for use by all clinical practitioners, the module covers:

- a description of important adverse effects
- factors that increase the risk of adverse effects
- how the clinician and the patient can reduce the risk
- specific treatment of the adverse effect

Used with authoritative clinical information and treatment guidelines, this module is a key practical aid to doctors, pharmacists and nurses.

Our learning module incorporates a quiz on important risks and their management. Participants will be able to download evidence of their learning.

The learning module on oral anticoagulants has been approved for up to 1.5 continuing professional development (CPD) credits by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom.

Education page of MHRA website
http://www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/index.htm

This oral anticoagulants learning module joins similar CPD-approved MHRA modules on antipsychotics, benzodiazepines, opioids, and selective serotonin reuptake inhibitors. You can access the full range of MHRA learning modules on devices and medicines through the education page of our website.

Article citation: Drug Safety Update volume 8 issue 1, August 2014: O1.