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 (MHRA) is the government agency 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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First, use materials now online to ensure women and girls taking valproate medicines meet the requirements of the new Pregnancy Prevention Programme. See page 2 for links to the electronic copies of the Patient Card, Patient Guide, Guide for Healthcare Professionals, and the Risk Acknowledgement Form.

Next, we remind you to train patients prescribed Braltus tiotropium capsules for chronic obstructive pulmonary disease on inhaler technique (page 3). Ensure patients know to place the Braltus capsule in the correct chamber of the Zonda inhaler. We have received reports of patients who have inhaled a Braltus capsule from the mouthpiece into the back of the throat, risking aspiration or airway obstruction.

Finally, read and act on an important Medical Device Alert (page 4) for Accu-Chek Aviva, Accu-Chek Performa, and Accu-Chek Inform II test strips. Affected strips, manufactured by Roche Diabetes Care, may give increased strip error messages prior to dosing with blood and in some cases may give false high or low readings, which may be hard to detect. See page 4 for the alert, which details the actions needed from healthcare professionals.

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Valproate medicines (Epilim▼, Depakote▼): Pregnancy Prevention Programme materials online

Use materials online now and hardcopies arriving over the coming weeks by post to ensure women and girls of childbearing potential on valproate medicines meet the requirements of the Pregnancy Prevention Programme.

Act now to use the following to support the new Valproate Pregnancy Prevention Programme:

- **Patient Card** – to be given by pharmacists to all female patients who are dispensed valproate medicines to inform them of the risks
- **Patient Guide** – to be provided to girls (of any age) and women of childbearing potential (or their parent/caregiver/responsible person) taking any medicine containing valproate
- **Guide for Healthcare Professionals** – for all prescribers, pharmacists, and other healthcare providers involved in the care of women and girls of childbearing potential using valproate medicines
- **Risk Acknowledgement Form** – for the specialist and patient (or their parent/caregiver/responsible person) to sign at initiation and at treatment reviews at least every year. The patient should receive a copy of the form; one copy should be filed in the specialist notes, and one copy sent to the patient's GP

You will be aware that an alert was issued last month about new prescribing and dispensing requirements for all valproate medicines (see April 2018 Drug Safety Update). The Marketing Authorisation Holder for Epilim has produced new materials to support the Pregnancy Prevention Programme – branded as Prevent. These are linked to above and will be sent by post to healthcare professionals in the coming weeks. Once received, please dispose of any old materials which you have remaining.

Stickers with warning symbols to attach to the pack for supply to the patient will be included in materials to pharmacists. This is pending the availability of new package labelling with the warning symbols.

Who should be on a Pregnancy Prevention Programme?

Valproate medicines must no longer be used in women or girls of childbearing potential unless a Pregnancy Prevention Programme is in place. The requirement for a Pregnancy Prevention Programme is applicable to all premenopausal female patients unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

Off-label use: restrictions and responsibilities still apply

Valproate is not licensed for treatment of conditions other than epilepsy or bipolar disorder in the UK. However, we are aware that these medicines are sometimes used off-label (for example, in migraine prophylaxis). All women and girls of childbearing potential should meet the conditions of a Pregnancy Prevention Programme, irrespective of indication. All prescribers should be aware of their responsibilities when prescribing medicines off-label (see Drug Safety Update for more information).

Share best practice

Many organisations and groups have already taken steps to embed these recommendations into clinical practice. Resources are or soon will be available from professional bodies to assist you in ensuring these new prescribing and dispensing requirements are met.

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Braltus (tiotropium): risk of inhalation of capsule if placed in the mouthpiece of the inhaler

Train patients to place the Braltus capsule in the correct chamber of the Zonda inhaler. We have received reports of patients who have inhaled a Braltus capsule from the mouthpiece into the back of the throat, resulting in coughing and risking aspiration or airway obstruction.

Advice for healthcare professionals:

- train patients in the correct use of their inhaler; a placebo device is available for training purposes (see below) and instructions for patients are provided in the patient information leaflet and on the carton
- tell patients to store capsules in the screw-cap bottle provided (never in the inhaler) and to always check the mouthpiece is clear before inhaling
- pharmacists dispensing Braltus capsules should remind patients always to read the instructions for use in the package leaflet and that they must never place a capsule directly into the mouthpiece
- please continue to report adverse incidents during use of the inhaler as well as suspected adverse reactions to the medicine on a Yellow Card

Background

Braltus tiotropium 10 µg per delivered dose inhalation powder is a once-a-day maintenance bronchodilator treatment authorised to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD). The inhalation powder is provided in capsules for inhalation using the Zonda inhaler device.

Reports of patients who have inhaled capsules into the back of the throat

We have received 2 Yellow Card reports of patients who have inhaled a Braltus capsule from the mouthpiece into the back of the throat. Both patients coughed up the capsule and recovered from the event. Health professionals have also observed that some patients have placed the capsule into the mouthpiece during training to use the inhaler device.

It is essential that patients know never to place a capsule directly into the mouthpiece (see diagram in package leaflet). To obtain a placebo device, please contact Teva Medical Information on medinfo@tevauk.com or call 0207 540 7117.

Call for reporting

Please continue to report adverse incidents during use of the inhaler, as well as suspected adverse reactions to the medicine, on a Yellow Card.

Medication incidents where no harm has occurred should continue to be reported via local risk management systems.

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Letters sent to healthcare professionals in April 2018

In April 2018, letters were sent to healthcare professionals about:

- Risk of mix-ups between insulin Fiasp (fast-acting insulin aspart) and Tresiba (basal insulin degludec)
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- Inhixa (enoxaparin sodium) solution for injection: rare cases of self-activation of safety device in unopened, unused pre-filled syringes

Finally, complete this 10-minute survey to tell us your views on the way medicines safety issues are communicated and how we might improve this to better support safe and effective use.

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Medical Device Alerts issued in April 2018; recent alert about Accu-Chek blood glucose test strips

In this monthly update, we highlight selected Medical Device Alerts that have been issued recently by MHRA. Please note, this is not an exhaustive list of medical device alerts. For all Medical Device Alerts from MHRA, see Alerts and recalls for drugs and medical devices.

Alerts were recently issued by MHRA about:

- Home use and Point of Care blood glucose monitoring system: Accu-Chek Aviva, Accu-Chek Performa and Accu-Chek Inform II test strips – risk of strip error messages and false high and low blood glucose results

- Infinity Acute Care System and M540 Patient Monitors software versions VG2.2-VG6.0 – risk that alarms are not activated

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