NORTHERN IRELAND
MEDICINES MANAGEMENT

Health and Social Care Board

Inhaler Supplement

Braltus Zonda - Cost-Effective Tiotropium Prescribing

May 2019

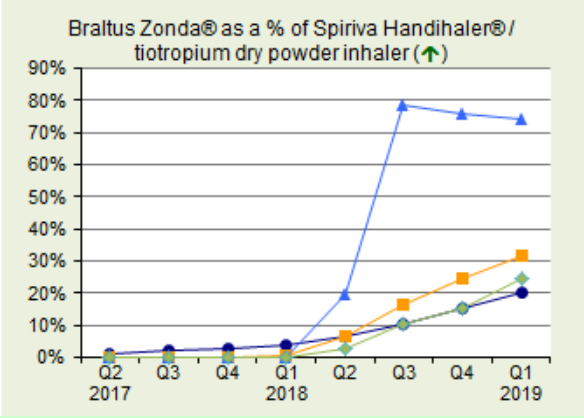
Switching tiotropium dry powder inhalers to Braltus Zonda®: What two local GP Practices did

Braltus Zonda® was recently added to the cost-effective choices (CEC) list as an alternative to Spiriva Handihaler®. It is a similar device, bioequivalent, and could provide **estimated savings of £1m per annum (Oct-Dec 2018 data)** if adopted across Northern Ireland. Many practices have successfully completed the switch. Two of these practices decided to make the switch as one of the benefits is that the patient receives a new device each month. The two practices utilised different approaches when implementing the change and have shared information on how they made the switch with HSCB.

PRACTICE A

A search was carried out by the practice based pharmacist (PBP) and identified 37 suitable patients. The list was reviewed by the practice nurse, and face-to-face appointments were arranged for 6 patients to provide additional support. The remaining patients were issued letters explaining the switch, records amended to Braltus® and an information leaflet attached to the first prescription. The local community pharmacies were contacted and informed about the change to Braltus® and asked to help demonstrate inhaler technique for the new product if required. Practice staff were given all relevant information and asked to direct any medication queries to the PBP or practice nurse.

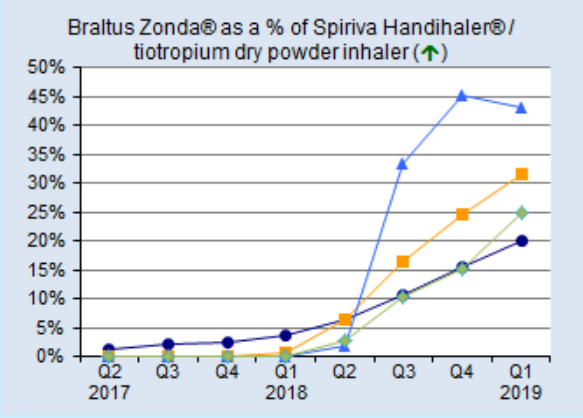
PRACTICE A



PRACTICE B

All clinicians within the practice agreed for the switch to be undertaken. The practice felt the best way to undertake this was for the practice nurse to change appropriate patients at face to face consultations. The practice nurse explained the switch, amended patient records, demonstrated inhaler technique and gave out information leaflets to appropriate patients. Over the course of 4 months the practice nurse switched 30 of 45 suitable patients. The remaining 15 will be changed over the next few months. The local community pharmacies were contacted explaining the switch so any queries could be answered, and to ensure stock was available. Practice staff were given information about the switch and asked to direct any medication queries to the practice nurse.

PRACTICE B



Recommendations to other GP practices:

The GP practice needs to agree how best to undertake the switch, i.e. via letter, by face to face consultations or a combination of both.

It is useful to have a coordinated approach and make sure everyone is fully briefed on the switch and their role in the process. In particular, ensure that the admin team are well briefed (as they are the first point of contact) with clear directions about what is being replaced and who to direct queries to, so that the switch can go smoothly and that the local pharmacies are contacted to ensure stock is available.

MHRA Alert: Risk of inhalation of capsules

In May 2018 the MHRA issued an alert on two Yellow Card reports of patients who had inhaled a Braltus® capsule from the mouthpiece into the back of the throat. In both instances the patients coughed up the capsule and recovered from the event with no harm.
Both practices overleaf undertook the switch after the MHRA alert and have received no reports of patients inhaling a Braltus® capsule from the device mouthpiece.

MHRA advice on Braltus Zonda® inhaler:

- MHRA agreed no device modifications were necessary
- The product information (SmPC, PIL and labelling) should be updated to ensure that information instructing healthcare professionals and patients /carers on the correct use of the product (in terms of where to place the capsule in the inhaler), is appropriately advocated and patients are being trained accordingly
- All the updates required to the Braltus® (tiotropium) patient materials by the MHRA where completed as of September 2018.

MHRA advice for healthcare professionals:

- Train patients on the correct use of their inhaler; a placebo device is available for training purposes 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 to always 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 regarding use of the inhaler as well as suspected adverse reactions to the medicine on a Yellow Card.

Resources available to help with the Braltus® switch

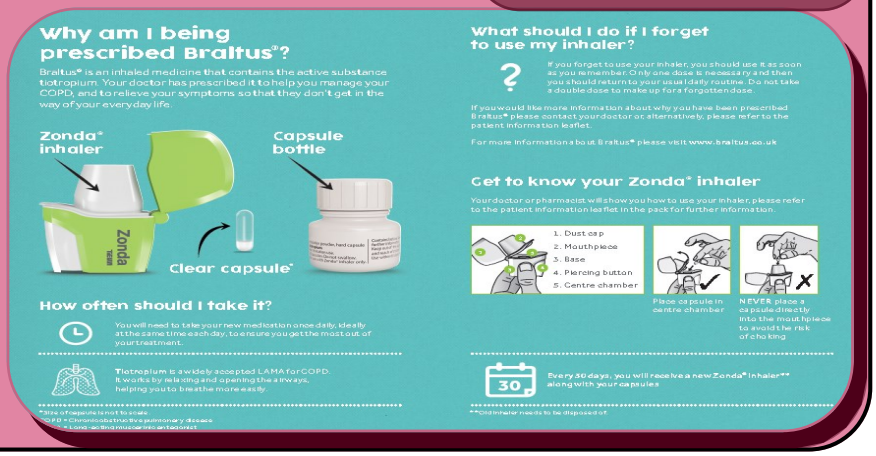
A range of resources have been made available on the Primary care intranet site including:

- HSCB Braltus Zonda PIL
- HSCB Braltus Zonda Cost Effective Choice SOP

Further resources are also available from Teva by contacting Audrey Campbell: **Audrey.Campbell02@tevauk.com**

Resources include:

- Tear off information sheets
- Information sheet (for patients already on a product)
- Information sheets (for newly initiated patients)



This newsletter has been produced for GPs and pharmacists by the Regional Pharmacy and Medicines Management Team.