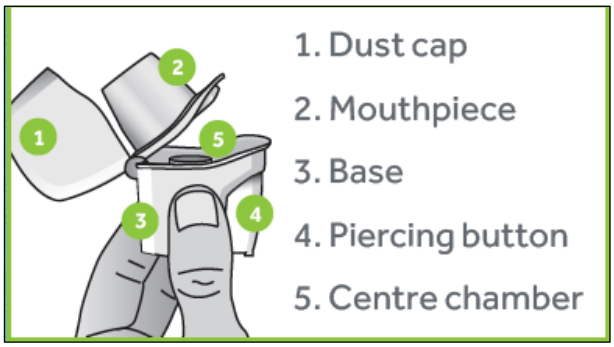
NHS
Midlands and Lancashire
Commissioning Support Unit

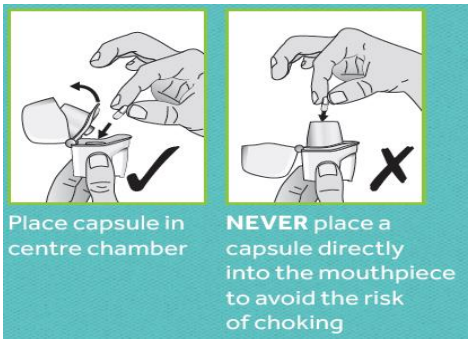
Inhalation of Braltus Capsules - MHRA warning



MHRA Safety Warning – Risk of inhalation of capsule if placed in the mouthpiece of the inhaler.

The Braltus inhalation capsules with Zonda inhaler contains Tiotropium and is the new more cost effective replacement to the Spiriva Handihaler, used for COPD. In May 2018 a drug safety warning[1] was issued by the Medicines and Healthcare products Regulator Agency as they had received two yellow card reports of patients who had inhaled a capsule from the mouthpiece of the device into the back of the throat. In addition to these yellow card reports, other health professionals have observed patients putting the capsule into the mouthpiece when training them how to use it.

There are several good resources available to the patient to instruct them correctly on how to use the device, including a step-by-step method found in the patient information leaflet inside the product, large clear images and video demonstration on the Braltus website www.braltus.co.uk which includes a demonstration by a healthcare professional using a placebo device.



Key tips for the patient:

- ✓ Only use the Zonda inhaler with the Braltus capsules.
- ✓ Never place the capsule directly into the mouthpiece
- ✓ Do not reuse the device with another bottle of Braltus capsules (a new device will be provided with each new bottle of Braltus capsules)
- ✓ The capsule is transparent so the patient can check that the contents have been inhaled after use.
- ✓ Always check the mouthpiece is clear before inhaling.

To request a placebo device contact Teva medical information on medinfo@tevauk.com.

Reference
1. https://www.gov.uk/drug-safety-update/braltus-tiotropium-risk-of-inhalation-of-capsule-if-placed-in-the-mouthpiece-of-the-inhaler

To contact the Medicines Optimisation Team please phone 01772 214302