



Ireland

Teva Pharmaceuticals Ireland

www.teva.ie

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2nd January 2017

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION:**

**Braltus (tiotropium) 10 microgram per delivered dose inhalation powder, hard capsule,**  
PA1986/006/001

**Advice to minimise the risk of medication error**

Dear Healthcare Professional,

In agreement with the Health Products Regulatory Authority (HPRA), Teva Pharmaceuticals Ireland is sending this communication in order to highlight differences in how the active ingredient content is presented on the Braltus product information, compared with the originator product (pre-metered vs delivered dose), with a view to minimising any potential risk of medication error.

**Summary**

- A new formulation of tiotropium bromide inhalation powder, presented in a new inhaler device (Braltus 10 microgram per delivered dose inhalation powder, hard capsule), has been approved for use in Ireland.
- Should prescribers make a decision to switch patients between the originator product (Spiriva®-tiotropium bromide) and Braltus, there is a potential risk of medication errors if the dosing instructions are misunderstood. This letter highlights the correct use of the new product to minimise this risk.
- The pre-metered dose of tiotropium in Braltus (13 mcg) is lower than the pre-metered dose of Spiriva® (18 mcg), **however the 'delivered doses' (i.e. dose delivered to the patient) of both products are the same (10 mcg).**
- The carton for Braltus states the delivered dose 10 mcg on the front, but also includes both the pre-metered and delivered doses of tiotropium (13 mcg and 10 mcg respectively) on the side, while for Spiriva® the carton states only the pre-metered dose of tiotropium (18 mcg).
- It is important to note that **both products provide the same delivered dose of tiotropium to the patient and the dosing regimen of one capsule, once daily, is the same with both products.**

**Further information**

Braltus is indicated in adults as a maintenance bronchodilator treatment to relieve symptoms in patients with chronic obstructive pulmonary disease (COPD). The recommended dose in adults (18 years and older) is one capsule taken once daily with the Zonda inhaler.

Braltus contains a smaller amount of tiotropium bromide in its capsules than the originator product Spiriva®, **but provides an equivalent amount of tiotropium (the delivered dose).**

**Teva Pharmaceuticals Ireland**

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Teva Pharmaceuticals Ireland is a registered business name of Norton (Waterford) Limited.  
Registered Office is Unit 301, Industrial Park, Cork Road, Waterford, Republic of Ireland.

Norton (Waterford) Limited is a private company limited by shares registered in Ireland under registration number 100363  
Directors: Theodorus Andriessen (Netherlands), Andy Crowley, Leonie Forristal



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The table below illustrates how the products differ:

Variable	Braltus	Spiriva®
Active capsule contents*	16 mcg tiotropium bromide	22.5 mcg tiotropium bromide monohydrate
Tiotropium equivalent (pre-metered dose)	13 mcg tiotropium	18 mcg tiotropium
Delivered dose	<b>10 mcg tiotropium</b>	<b>10 mcg tiotropium</b>
Dosing regimen	<b>One capsule, once daily</b>	<b>One capsule, once daily</b>

\*Please note that this information is not available to the patient in the patient information leaflet

It is important to note that if patients are being switched between Spiriva® and Braltus, the dosing schedule of **one capsule, once daily remains the same and does not change.**

### Call for reporting

You are reminded to report any suspected adverse reactions in accordance with the national spontaneous reporting system via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +3531 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

For further inquiries concerning this information, please contact Teva's Medical Information Department as follows:  
Email: medinfo@tevauk.com; Tel: +44 (0) 207 540 7117

### Company contact point

Adverse reactions concerning Braltus may also be reported to Teva Ireland Pharmacovigilance via Email: safety.ireland@teva.ie; Tel: +353 51 321538 or +353 87 677 3650; Fax: +353 51 359805; Website: www.teva.ie

Should you have any other queries, please contact your local Teva sales representative or call the Teva Customer Care Team on Freephone 1800 201700.

Yours faithfully,

*Dr Greg Hays*

Dr Greg Hays, Head of Medical Affairs

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