

7<sup>th</sup> October 2019

**IMPORTANT INFORMATION AND NOT PROMOTIONAL MATERIAL – PLEASE READ**

**RE: Volibris (ambrisentan) new patient alert card and removal of the controlled distribution system**

Dear Healthcare Professional,

The European Medicines Agency (EMA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA) have approved changes to the marketing authorisations for Volibris 5 mg film coated tablets, Volibris 10 mg film coated tablets (EU/1/08/451/001-004) - (ambrisentan) to:

- remove the requirement for a controlled distribution system
- remove the need for the Volibris Healthcare Professionals User Guide, Patient Booklet and the Card for the partners of PAH Patients
- introduce a new Patient Alert Card which will support the continued need to perform liver function tests to monitor patients for possible hepatotoxicity, and pregnancy tests for women of child bearing potential to prevent exposure to the teratogenic effects of ambrisentan during pregnancy

**These changes will be effective from the 7<sup>th</sup> of October 2019.**

The new Patient Alert Card will be provided to all designated PH centres to give to patients in the clinic. In addition, a copy of the Patient Alert Card will be provided along with each pack of Volibris by Alliance Healthcare (the single wholesaler for the distribution of Volibris in the UK), thus ensuring that existing Volibris patients receive the card on a regular basis. The Patient Alert Card will also be available on the Electronic Medicines Compendium (eMC) website from which further copies can be downloaded and/or printed, via the following link:

Volibris Patient Alert Card: <https://www.medicines.org.uk/emc/rmm/1594/Document>

Copies of the Volibris Summary of Product Characteristics and Volibris Patient Information Leaflet are also available on the eMC website via the following links:

Volibris SmPC: <https://www.medicines.org.uk/emc/product/9036/smpc>

Volibris PIL: <https://www.medicines.org.uk/emc/product/9036/pil>

These changes were approved based on (i) the restricted use of ambrisentan by specialist PH physicians who are now very familiar with the product, its benefit risk profile and the need for routine monitoring of patients (ii) the known and characterised safety profile of ambrisentan.

If you have any medical queries regarding this change, please contact our Medical Information Department on +44 (0)800 221 441, 8:30am to 5:30pm GMT Monday - Friday. An out of hours service is also provided for emergencies which goes to an external provider outside of the times stated.

If you have any supply related queries regarding Volibris please contact our Customer Support Team on +44 (0)800 221 441.

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.

Yours sincerely,



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