Roche Products Ltd
6 Falcon Way, Shire Park
Welwyn Garden City
AL7 1TW
Registered in England No. 100674

April 2015

Dear Healthcare Professional

Esbriet (pirfenidone) 267mg capsules

Product Availability

Roche Products Ltd., in agreement with the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), wishes to inform you about relevant safety information concerning the use of Esbriet®▼ (pirfenidone).

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SUMMARY

Esbriet (pirfenidone) 267mg/capsules has recently become available in Malta for the treatment of adults with mild to moderate idiopathic pulmonary fibrosis (IPF).

Please find attached the Safety Checklist for your reference which highlights some key warnings. You should always read the current version of the SmPC for full information.

INDICATION FOR USE

Esbriet (pirfenidone) 267mg capsules is authorised for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF). This treatment should be used in adults only. Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of IPF.

We trust that the enclosed information will assist you in using Esbriet to manage your patients appropriately.

We would like also to remind you of the importance of Healthcare Professionals to report suspected adverse reactions in accordance with your national adverse event reporting system.

If you require further information about Esbriet or have a question about any aspect of this letter, please contact Roche Medical Information on: +44 800 328 1629.

Please take time to read the Summary of Product Characteristics for Esbriet, which is enclosed.

Yours faithfully,

Catherine Huertas

Medical Manager

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▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal

Adverse events should also be reported to InterMune UK & I Limited, a member of the Roche Group:
Tel: +44 (0) 203 514 0675, Fax: +44 (0)3308 080969, Email: med-info@intermune.co.uk

This educational material is provided by Roche Products Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks