ASSOCIATED DRUG COMPANY LIMITED
TRIQ L-ESPORTATURI, MRIEHEL, BIRKIRKARA BKR 3000, MALTA
TEL: 2277 8000 FAX: 2277 8120

20th March 2014

Peginterferon alfa-2b, ViraferonPeg, Introduction of the newClearclick pre-filled pen device

Dear Healthcare professional,
Merck Sharp &Dohme(MSD), in agreement with the European Medicines Agency and the national competent Authority,would like to inform you of the following:

Summary

- Beginning January 2014, MSD will introduce the newViraferonPegClearclick pre-filled pen.
- This is an injection device that will replace the existing pre-filled pen device. Only the injection device will change. There will be no change to the drug product/diluent cartridge.
- To ensure correct use of the new Clearclick pre-filled pen device, patients who are currently on treatment or who are about to start treatment with ViraferonPeg would need to be appropriately informed and trained.
- It is expected that some stock of the current pre-filled pen device will continue to be available for approximately 3 months after initial introduction of the new Clearclick pre-filled pen device, although the exact time will depend on the amount of available stock on national markets and its expiration date. MSD will make every effort to help minimise stocks of the previous device at the time of Clearclick distribution.

Further recommendations

Patients who currently use ViraferonPegshould be changed over to the newClearclick pre-filled pen device.

New patients should be started with a prescription for the new Clearclick pre-filled pen device.

In an effort to ensure that new and existing patients not only receive their prescription without interruption but also do not miss a dose, we ask that you inform patients of this transition and train the patients on the new Clearclick pre-filled pen device as soon as possible.

MSD is committed to making this transition smooth for both you and your patients. Support materials are available for you to use to counsel patients on how to use the new Clearclick pre-filled pen device. You should also refer patients to the Instructions for Use, which provides step-by-step instructions for patients on how to use the new Clearclickpre-filled pen device.

For additional information on the transition from the current pre-filled pen device to new Clearclick pre-filled pen device, or for additional support materials, please contact your MSD representative (MSD Cyprus Ltd tel. no. 8007 4433 in Malta).

Further information

Therapeutic indication of the medicinal product

Adults (tritherapy)

ViraferonPegin combination with ribavirin and boceprevir (tritherapy) is indicated for the treatment ofchronic hepatitis C (CHC) genotype 1 infection in adult patients (18 years of age and older) with

compensated liver disease who are previously untreated or who have failed previous therapy (seesection 5.1).
Please refer to the ribavirin and boceprevir Summary of Product Characteristics (SmPCs) when ViraferonPegis to be used in combination with these medicines.

Adults (bitherapy and monotherapy)
ViraferonPegis indicated for the treatment of adult patients (18 years of age and older) with CHC who are positive for hepatitis C virus RNA (HCV-RNA), including patients with compensated cirrhosis and/orco-infected with clinically stable HIV (see section 4.4).

ViraferonPegin combination with ribavirin (bitherapy) is indicated for the treatment of CHC infection in adult patients who are previously untreated including patients with clinically stable HIV co-infectionand in adult patients who have failed previous treatment with interferon alpha (pegylated ornonpegylated) and ribavirin combination therapy or interferon alpha monotherapy (see section 5.1).

Interferon monotherapy, including ViraferonPeg, is indicated mainly in case of intolerance or contraindication to ribavirin.

Please refer to the ribavirin SmPC when ViraferonPegis to be used in combination with ribavirin.

Paediatric population (bitherapy)
ViraferonPegis indicated in a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, previously untreated, without liver decompensation, and who are positive for HCV-RNA.

When deciding not to defer treatment until adulthood, it is important to consider that the combinationtherapy induced growth inhibition that may be irreversible in some patients. The decisionto treat should be made on a case by case basis (see section 4.4).

Please refer to the ribavirin SmPC for capsules or oral solution when ViraferonPegis to be used incombination with ribavirin.

Call for reporting
MSD encourages any feedback regarding the product and/or device.

Please report adverse reactions and medication errors in accordance with the national spontaneous reporting system.

ADR forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and sent to, ADR reportingThe Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira, or emailed to: postlicensing.medicinesauthority@gov.mt

Company contact point
Adverse events can alsobe reported to MSD Cyprus Ltd (tel. no. 8007 4433 in Malta).

References
The product information (SmPC, Patient Information Leaflet and Instruction for Use) have been revised. The distribution will follow adoption of the Commission Decision.

Detailed information on this medicine is available on the European Medicines Agency web site:http://www/ema.europa.eu.

Annexes
The following annexes are attached to the present communication:

- Instructions for Use.
- Summary of Product Characteristics

Yours Faithfully,

Samantha Camilleri
Drug Safety Responsible