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September 2013

Peginterferon alfa-2b, ViraferonPeg, Introduction of the new Clearclick pre-filled pen device.**Dear Healthcare professional,**

Merck Sharp & Dohme (MSD), in agreement with the European Medicines Agency and the Irish Medicines Board, would like to inform you of the following:

Summary

- Beginning October 2013, MSD will introduce the new ViraferonPeg Clearclick 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 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 ViraferonPeg should be changed over to the new Clearclick 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 Clearclick pre-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.

Further information**Therapeutic indication of the medicinal product**Adults (tritherapy)

ViraferonPeg in combination with ribavirin and boceprevir (tritherapy) is indicated for the treatment of chronic 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 (see section 5.1).

Please refer to the ribavirin and boceprevir Summary of Product Characteristics (SmPCs) when ViraferonPeg is to be used in combination with these medicines.

Adults (bitherapy and monotherapy)

ViraferonPeg is 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/or co-infected with clinically stable HIV (see section 4.4).

ViraferonPeg in 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-infection and in adult patients who have failed previous treatment with interferon

alpha (pegylated or nonpegylated) 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 ViraferonPeg is to be used in combination with ribavirin.

Paediatric population (bitherapy)

ViraferonPeg is 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 combination therapy induced growth inhibition. The reversibility of growth inhibition is uncertain. The decision to 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 ViraferonPeg is to be used in combination with ribavirin.

Call for reporting

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

Suspected adverse reactions should be reported to the IMB using a Yellow Card obtained either from the IMB, or electronically via the website at www.imb.ie. Adverse reactions can also be reported by calling on (01) 6764971.

Company contact point

MSD
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References

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

Sincerely,



Dr. Colm Galligan MB MSc MBA MFPM
Medical Director

Annexes

The following annexes are attached to the present communication:

- Instructions for Use

INSTRUCTIONS FOR USE

How to use the ViraferonPeg pre-filled pen

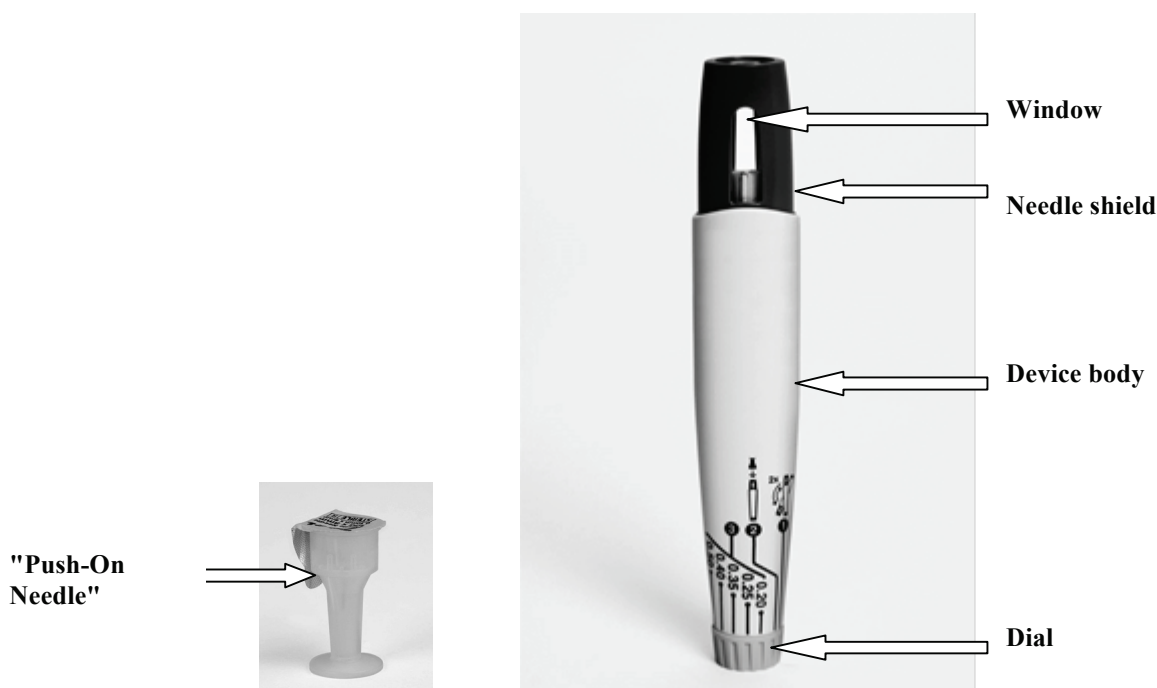
The following instructions explain how to use the pre-filled pen to inject yourself. Please read the instructions carefully and follow them step by step. Your healthcare provider will instruct you on how to give the injections. Do not attempt to administer an injection until you are sure you understand how to use the pre-filled pen. Each pre-filled pen is for single use only.

Getting ready

- Find a well-lit, clean flat work surface such as a table.
- Take the pre-filled pen out of the refrigerator. Look at the date printed on the carton after EXP to make sure that the expiration date has not passed. Do not use if the expiration date has passed.
- Remove the pre-filled pen from the carton.
- Lay the pre-filled pen on a flat clean surface and wait until it reaches room temperature (but not more than 25°C). This may take up to 20 minutes.
- Wash your hands well with soap and warm water. Keep your work area, your hands, and the injection site clean to decrease the risk of infection.

You will need the following supplies that are included in the package:

- a pre-filled pen (CLEARCLICK)
- a needle ("Push-On Needle")
- 2 alcohol swabs



1. Mix

- Hold the pre-filled pen upright with the dial on the bottom.
- Turn the dial to number 1 (see Figure 1). You may hear a "click" sound.



Figure 1

- DO NOT SHAKE TO MIX. Gently turn the pre-filled pen up-side-down two times to mix (see Figure 2).



Figure 2

- Look in the window. The solution should be clear and colourless before use. Some bubbles may be present, but this is normal. Do not use if it is discoloured or if particles are present.

2. Add needle

- Turn the dial to number 2 (see Figure 3). You may hear a "click" sound.



Figure 3

- Wipe the top of the pre-filled pen where the needle is going to be attached with an alcohol swab (see Figure 4).



Figure 4

- Remove the yellow paper from the needle cap before attaching the needle ("Push-On Needle") to the pre-filled pen (see Figure 5),



Figure 5

- Support the pre-filled pen in upright position and push the needle straight down firmly (see Figure 6). You might hear a soft sound when pushing on the needle.

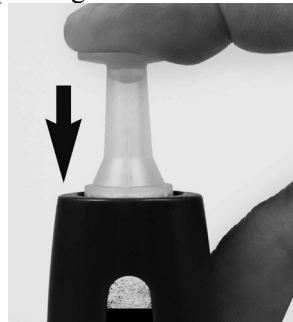


Figure 6

- Remove the needle cap. You may see some liquid trickle out of the needle (see Figure 7). This is normal.

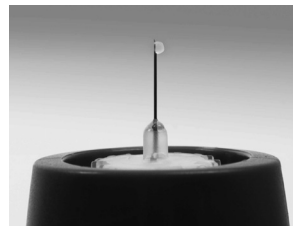


Figure 7

3. Dial dose

- Turn the dial to **your prescribed dose** (see Figure 8). You may hear clicking sounds as you dial. Note: The needle shield will automatically SNAP UP as you dial (see Figure 9). You may dial up or down to any dose prior to injection.



Figure 8

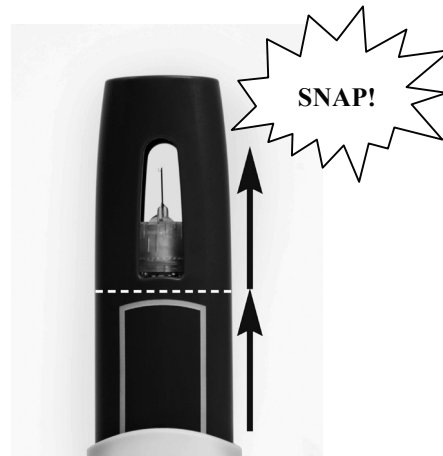


Figure 9

You are ready to inject

- Choose an injection site on your stomach area (abdomen) or thigh. Avoid your belly button (navel) and waistline. If you are very thin, you should only use the thigh for injection. You should use a different place each time you give yourself an injection. Do not inject ViraferonPeg into an area where the skin is irritated, red, bruised, infected, or has scars, stretch marks, or lumps.
- Wipe the injection site with a new alcohol swab. Let the skin air dry.
- Pinch a fold of loose skin in the area you have cleaned for injection.
- Press the pre-filled pen against the skin as shown in Figure 10. The shield will automatically glide back to allow the needle to inject the medicine.
- **Hold the pre-filled pen against the skin for 15 seconds.** Note: The pre-filled pen will make a clicking sound for up to 10 seconds – depending on your dose. Additional 5 seconds ensures complete dose delivery.

Note: Once the pre-filled pen is removed from the skin, the needle shield will lock in place.



Figure 10: Thigh injection

Disposal of the injection materials

The pre-filled pen, needle and all injection materials are intended for single use and must be discarded after the injection. Dispose of the used pre-filled pen safely in a closed container. Ask your healthcare provider or pharmacist for an appropriate container.