IPSEN
Innovation for patient care

January 2016

Important information for healthcare professionals

Addition of a subcutaneous route of administration for Decapeptyl 3 Month (triptorelin pamoate) for **male patient's only** to the existing marketing authorisation of intramuscular route

Active substance(s) Triptorelin pamoate
Product name, strength, pharmaceutical form: Decapeptyl 3-month, 11.25mg powder and solvent for suspension for injection
Product authorization number(s) PA 869/003/002

Dear Healthcare Professional,

Ipsen Pharmaceuticals Ltd. would like to inform you of the following changes:

- The addition of a subcutaneous route of administration for **male patient's only** to the existing Marketing Authorization authorised with intramuscular route; allowing physicians and male subjects to have the flexibility to choose and tailor treatment by balancing preferences (subcutaneous or intramuscular route of administration) currently available for other GnRH agonists (leuprorelin).
- Furthermore, the addition of a specific needle for subcutaneous injection (25 mm in length) in the injection kit.
- Moreover, in order to be in line with the requirements of the European Directive 2010/32/EU on the prevention of sharp injuries in the hospital and healthcare sector, the current approved intramuscular injection needle and the added subcutaneous needle are equipped with a needle safety system.

The sterile injection kit will therefore be composed of one syringe and the following three needles:
- One needle for transferring the solvent for powder reconstitution (no change to this needle)
- One needle for intramuscular injection which will be ***equipped with a safety system*** (addition of the safety system on the current needle)
- ***One needle for subcutaneous injection also equipped with a safety system*** (new needle)

In addition to the changes outlined above, there is a parallel unrelated change to the product information with respect to, safety data from recent clinical studies and recent commercial experience which has resulted in updates to the adverse drug reaction (ADR tables) of the approved SmPC and PIL.

All of the above changes impact on the SmPC and Patient Information Leaflet (PIL) and labelling.

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The main changes to the **SmPC** are in the following sections:

Section 4.2 Posology and Method of Administration	Updated to include addition of subcutaneous route of administration for male adults
Section 4.8 Undesirable effects	Updates to ADR tables (including changing of frequencies of some ADR's)
Section 5.1 Pharmacodynamic properties	Updated study information relating to the addition of a sub-cutaneous route of administration in men
Section 5.2 Pharmacokinetic properties	Updated study information relating to the addition of a sub-cutaneous route of administration in men
Section 6.5 Nature and contents of container	Updated to include details of the additional needle
Section 6.6 Special precautions for disposal and other handling	Updated instructions for reconstitution including information on subcutaneous injection

Changes to the **PIL** are in alignment with the SmPC changes. The main changes to the PIL are in the following sections:

Section 3 How to use Decapeptyl 3-month	Updated to include addition of subcutaneous route of administration for male adults
Section 4. Possible side effects	Updates to ADR tables (including changing of frequencies of some ADR's)
Section 6 Contents of the pack and other information	Updated to include details of the additional needle
Instructions Reconstitution for HCP	Updated reconstitution instructions for HCP based on additional route of administration, additional needle and equipment of needles with a new safety system

The main changes to the **Carton** are as follows:

- Updated to include addition of subcutaneous route of administration for male adults
- Updated to include details of additional needle and syringe.

The main change to the **Vial Label** is as follows:

- Updated to include addition of subcutaneous use (SC use) for male adults

Please ensure that all relevant staff are made aware of the content of this letter and that the information is communicated to all relevant healthcare professionals within your practice as appropriate.

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

Please note that following approval of the above changes by the HPRA, there will be a time lag as per usual before these changes are actually implemented into the packs on the marketplace.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Adverse events should also be reported to Ipsen Medical Information Department on +35318098256 or medical.information.uk@ipsen.com

If you have any questions, please contact Ipsen Pharmaceuticals Ltd, Blanchardstown Industrial Park, Dublin 15, Ireland. Phone +353 1 809 8256.

Yours sincerely,

Dr. Matthew Hickling,
UK and Ireland Medical Director,
Ipsen Pharmaceuticals Ltd.