



IAL SYSTEM AND IAL SYSTEM ACP: INFORMATION NOTE

Starting from batch nr. 0176-00 of IAL SYSTEM 1.1 ML and batch nr. 0130-10 of IAL SYSTEM ACP, some changes have been performed to the packaging and accessories of such devices in order to improve their use and optimize the packaging process. These changes concern:

- 1) Increase of the dimension of the syringe blister and application of the back stop directly on the syringe.
- 2) Consequent increase of the box size and adhesive label for the traceability by batch and expiry date outside of the box.
- 3) The use of Sterimedix needles in rigid blister instead of Becton Dickinson needles in soft blister.

No change occurred in the preparation steps of the solution, filling and sterilization of the syringe. Therefore the characteristics of the viscoelastic solution did not undergo any change.

The application of back stop, directly on the syringe, facilitates the use of the product by the physician and shortens the necessary time to prepare the treatment. Moreover, the new needles are specifically designed for dermal injections by the British firm Sterimedix, one of the leading manufacturers in the world market of such devices.

In particular, new needles, while maintaining the external diameter unchanged, have a larger internal lumen, thereby supporting the extrusion of viscoelastic solutions and reducing the force to be applied to the plunger for the leakage of the solution.


The application is therefore easier and gives a better comfort both for the user and the patient, and the distribution of the solution is more uniform in the skin.

Fidia proceeded to test new needles confirming both the optimal coupling to the syringe and the easier extrusion.

The performed changes have been made with the aim of improving the overall quality of the Products and Processes, in order to better satisfy the needs of customers in a changing market.

Faithfully,

Fidia Farmaceutici S.p.A.


Cynthia Secchieri
Qualified Person

Abano Terme, 24 January 2011