

“Quick Notes”

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FDA Hepatitis Update - Pegasys (peginterferon alfa-2a) new disposable autoinjector

On September 29, 2011, the Food and Drug Administration approved a 135 mcg/0.5ml and 180 mcg/0.5 ml disposable autoinjector (DAI) to administer Pegasys (peginterferon alfa-2a), an antiviral indicated for treatment of Chronic Hepatitis C (CHC) by subcutaneous injection.

Pegasys continues to be available in a vial or prefilled syringe, and now also in a 135 mcg/0.5ml and 180 mcg/0.5 ml PEGASYS disposable autoinjector. The package insert and the Medication Guide have been updated to provide new information and instructions for use related to the disposable autoinjector.

Because the autoinjectors are designed to deliver the full content, autoinjectors should only be used for patients who need the full dose (180 or 135 mcg). If the required dose is not available in an autoinjector, prefilled syringes, or vials should be used to administer the required dose. The autoinjector is for subcutaneous administration only.

The updated label and Medication Guide can be found on the FDA web site at:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103964s5204lbl.pdf

If you have any questions please feel free to give us a call at 315.829.3604.