Generic Name:
Leuprolide acetate
Trade Name:
Lupron Depot-PED
Company:
Abbott
Notes:

Abbott announced the approval of a new formulation of leuprolide acetate: depot suspension 11.25 mg and 30 mg for 3-month administration in children with central precocious puberty. The product was previously approved for 1-month dosing in 7.5 mg, 11.25 mg, and 15 mg dosage strengths.

Approval was based on data from a 24-week study. It showed that two injections given 12 weeks apart resulted in sustained hormone suppression. In addition, the onset of hormone suppression was consistent with the 1-month formulation of leuprolide acetate in patients who had not been previously treated for central precocious puberty.

The most common adverse events with depot leuprolide are injection-site pain and swelling, weight gain, headache, and altered mood. This new formulation is expected to be available in late August.

Medication Monitor Categories:
Supplemental Approvals
Use:

Treatment of children with central precocious puberty