Livalo® (pitavastatin) – Expanded indication

- On May 16, 2019, the FDA approved Kowa Pharmaceuticals' Livalo (pitavastatin), as an adjunctive therapy to diet in pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH) to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and apolipoprotein B (Apo B).

    — Livalo was previously approved in adult patients with primary hyperlipidemia or mixed dyslipidemia to reduce elevated TC, LDL-C, Apo B, triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).
    — The effect of Livalo on cardiovascular morbidity and mortality has not been determined.

- The approval of Livalo's expanded indication was based on a double-blind study in 82 pediatric patients with genetically confirmed HeFH. Patients were randomized to placebo or Livalo.

    — Livalo significantly reduced plasma LDL-C, non-HDL-C, TC, and Apo-B vs. placebo. The reductions in LDL-C, Apo-B, TC, and non-HDL-C were dose dependent.
    — There was no statistically significant improvement in HDL-C or TG at any Livalo dose.

- The recommended starting dosage of Livalo in adult and pediatric patients aged 8 years and older is 2 mg once daily. The maximum recommended dosage is 4 mg once daily. Livalo can be taken with or without food at the same time each day.

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