

Recombivax HB[®], YF-Vax[®] – Drug shortages

The <u>drug shortages</u> of <u>Recombivax HB (hepatitis B vaccine, recombinant)</u> and <u>YF-Vax (yellow fever virus strain 17d-204 live antigen)</u> are ongoing. Recombivax HB and YF-Vax have been unavailable for at least 90 days.

Product Description	NDC #
Recombivax HB (hepatitis B vaccine, recombinant) 0.5 mL (5 mcg) pediatric/adolescent formulation single-dose vials and prefilled syringes	0006-4981-00, 0006- 4093-02, 0006-4093-09
Recombivax HB (hepatitis B vaccine, recombinant) 1 mL (10 mcg) adult formulation single-dose vials and prefilled syringes	0006-4995-00, 0006- 4995-41, 0006-4094-02, 0006-4094-09
YF-Vax (yellow fever virus strain 17-d- 2014 live antigen) single- and multi- dose vials	49281-0915-01, 49281- 0915-05

- The shortage of Recombivax HB is due to increased global demand.
- The Recombivax HB pediatric/adolescent and adult formulations are estimated to be available in the first half of 2018 and the first half of 2019, respectively.
- The Recombivax HB dialysis formulation is available; however, the dose is different than the adult and pediatric/adolescent formulations.
- YF-Vax is unavailable because the manufacturer, <u>Sanofi Pasteur</u>, is transitioning production to a new facility in 2018. YF-Vax is estimated to be available by mid-2018.
- Recombivax HB is indicated for prevention of infection caused by all known subtypes of hepatitis B virus.
 - Engerix-B[™] (hepatitis B vaccine, recombinant) is another currently available vaccine that carries the same indication as Recombivax HB. Engerix-B is not in shortage.
 - <u>Heplisav-B™</u> (hepatitis B vaccine, recombinant) was recently approved and carries the same indication as Recombivax HB. This product will not be commercially available until the first quarter of 2018.
 - Recombivax HB, Engerix-B, and Heplisav-B are not therapeutically equivalent.
- YF-Vax is indicated for active immunization for the prevention of yellow fever in persons 9 months of
 age and older in the following categories: persons living in or traveling to yellow fever endemic
 areas, persons traveling internationally through countries with yellow fever, and laboratory personnel
 who handle virulent yellow fever virus or concentrated preparations of the yellow fever vaccine virus
 strains.

— Sanofi Pasteur has worked with the FDA to make <u>Stamaril®</u> (yellow fever virus strain 17d-<u>204 live antigen</u>), a foreign, non-FDA approved drug available. Clinics providing access to Stamaril can be found <u>here</u>. Stamaril is not therapeutically equivalent to YF-Vax; however, the two products carry the same indication.



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