DYNAVAX
INNOVATING IMMUNOLOGY
2929 Seventh Street, Suite 100
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January 3, 2019

Heidi Gurov, RN
Wyoming Department of Health
Immunization Unit
6101 Yellowstone Road, Suite 420
Cheyenne, WY 82002

Dear Ms. Gurov,

The following information is being provided in response to your specific unsolicited request about HEPLISAV-B and "additional information on the use of Heplisav-B in pregnancy?"

Dynavax makes no recommendation on the use of HEPLISAV-B in any manner that is inconsistent with the approved labeling. Please refer to the enclosed HEPLISAV-B Package Insert for full prescribing and safety information.

There are no clinical studies of HEPLISAV-B in pregnant women. Available human data on HEPLISAV-B administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. In a developmental toxicity study, 0.3 mL of a vaccine formulation containing 2.5 mcg hepatitis B surface antigen (HBsAg) and 3000 mcg cytosine phosphoguanine (CpG) 1018 adjuvant was administered to female rats prior to mating and during gestation. These animal studies revealed no evidence of harm to the fetus due to this vaccine formulation.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to HEPLISAV-B during pregnancy. Women who received HEPLISAV-B during pregnancy are encouraged to contact 1-844-443-7734.

Thank you for your interest in HEPLISAV-B. If you have additional questions please contact Medical Information at 1-844-375-4728 or e-mail at Dynavaxmedinfo@lashgroup.com.

Kindest Regards,

Angela Henderson, RN
Dynavax Technologies Corporation
Case # DYN19-000002

ENCLOSURE

HEPLISAV-B [package insert]. Berkeley, CA: Dynavax Technologies Corporation; 2018.

REFERENCE

HEPLISAV-B [package insert]. Berkeley, CA: Dynavax Technologies Corporation; 2018.