PACKAGE INSERT – ACT HIB - Powder for injection vial and needle free diluent syringe

NAME OF THE MEDICINE

Act-HIB *Haemophilus* Type b Conjugate Vaccine (conjugated to tetanus protein)

Haemophilus Type b polysaccharide

DOSAGE FORM

Act-HIB is a freeze-dried powder for reconstitution with diluent for injection.

METHOD OF PREPARATION

Preparation:

Each single dose vial of Act-HIB contains freeze-dried powder which needs to be dissolved in 0.5 mL of the diluent for Act-HIB.

Slowly inject the entire contents of the diluent pre-filled syringe into the centre of the stopper on the vial. Shake vigorously until the freeze-dried powder is completely dissolved and a colourless solution is visible. Withdraw the entire contents of the reconstituted vaccine into the syringe and administer the total volume (about 0.5 mL) via the intramuscular or subcutaneous route. Aseptic technique must be used for withdrawal of each dose.

Compatibility:

DO NOT MIX Act-HIB IN THE SAME SYRINGE AS OTHER VACCINES OR MEDICINAL PRODUCTS. Once reconstituted, the vaccine must not be mixed with any other vaccine or medicinal product. Therefore, separate injection sites and different syringes should be used in case of concomitant administration.

Act-HIB can be incorporated into the recommended childhood immunization schedule, in accordance with the DTP schedule. However, the administration of Act-HIB should be carried out in a different site from those used for the other recommended vaccinations: Diphtheria, Tetanus, Pertussis, Poliomyelitis and Measles, Mumps and Rubella.

IN-USE STORAGE CONDITIONS

The reconstituted product must be used immediately after reconstitution.

SPONSOR

sanofi-aventis australia pty ltd
International Tower 3, Level 23
300 Barangaroo Avenue
Sydney NSW 2000
AUSTRALIA
Phone: 1800 818 806
Email: medinfo.australia@sanofi.com

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