DENGVAXIA® Abbreviated Prescribing Information (Version V03-21)

1. NAME AND PRESENTATION: DENGVAXIA is dengue tetravalent vaccine (live, attenuated) containing dengue virus serotypes 1, 2, 3 and 4, presented as powder in a single-dose vial and solvent in single-dose pre-filled syringe (0.5 mL), for suspension for injection.
2. THERAPEUTIC INDICATIONS: For protection against dengue disease caused by dengue virus serotypes 1, 2, 3 and 4, in adults, young people and children from 6 to 45 years of age with prior dengue virus infection confirmed by a test. The use of Dengvaxia should be in accordance with official recommendations
3. POSOLOGY AND METHOD OF ADMINISTRATION: Previous dengue infection must be confirmed by a test, either documented in the medical history or performed prior to vaccination. For child 6 to 45 years of age, the vaccine is given as 3 injections of 0.5 mL each at 6-month intervals by subcutaneous route in the upper arm. The first injection will occur at the chosen or scheduled date; the second injection, 6 months after the first injection; and the third injection, 6 months after the second injection. The powder and the solvent must be mix together before use.
4. CONTRA-INDICATIONS: Hypersensitivity to the active substances or any of the other ingredients, Allergic reaction after prior administration. Suffering from a disease with mild to high fever or acute disease, Weakened immune system eg, genetic defect, HIV infection, Therapies affecting the immune system (high-dose corticosteroids or chemotherapy), it is advisable to wait for at least 4 weeks before administration, Pregnancy and Breastfeeding.
5. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Not recommended for individuals who have never been infected by dengue virus before vaccination. Do not substitute for protection against mosquito bites. Do not use who have a mild to high fever or acute disease, ever had any health problems when given a vaccine, ever fainted from an injection, had any allergic reaction to latex. Not recommended in patients that never live in areas with dengue infections and patients that plan to travel in areas with dengue infection. Vaccine should not be administered in children less than 6 years of age.
6. DRUG INTERACTIONS: For patients receiving therapies affecting the immune system (high-dose corticosteroids or chemotherapy), it is advisable to wait for at least 4 weeks before administration. For patient receiving treatment with immunoglobulins or blood products containing immunoglobulins, such as blood or plasma, it is advisable to wait for at least 6 weeks, and preferably for 3 months, following the end of treatment before administration. Dengvaxia can be given at the same time as Diphtheria, Tetanus, Pertussis vaccine and recombinant Human Papillomavirus vaccines. Injections of more than one vaccine at the same time should be given at different injection sites.
7. PREGNANCY AND LACTATION: Vaccine must not be given to pregnant or breastfeeding women.
8. UNDESIRABLE EFFECTS: *Very Common*: Headache, Myalgia, Malaise, Injection site reactions: pain and redness (erythema). *Common*: injection site reactions: bruising (hematoma), swelling, and itching (pruritus). For uncommon, rare and very rare side effects see full prescribing information.
9. OVERDOSAGE: No cases of overdose have been reported in clinical studies.
10. PHARMACODYNAMIC PROPERTIES: Vaccines, Viral vaccines (ATC code: J07BX).
For more information, please see full prescribing information.