

# Patient Medication Guide Dengvaxia™

The information in this leaflet is for people who are being prescribed Dengvaxia™. Please talk to your doctor if you have any questions.

## ▪ **What is Dengvaxia and what is it used for?**

Dengvaxia is a vaccine used for the prevention of dengue disease caused by four strains of the dengue virus (serotypes 1, 2, 3 and 4). In Singapore, Dengvaxia is to be used only for individuals 12 through 45 years of age with test-confirmed previous dengue infection. It should not be administered in individuals less than 12 years of age and in individuals with no previous dengue infection.

## ▪ **Do not use Dengvaxia if you (or your child):**

- Are allergic (hypersensitive) to the active substances or any of the other ingredients of Dengvaxia,
- Have developed an allergic reaction after prior administration of Dengvaxia. Signs of an allergic reaction may include an itchy rash, shortness of breath and swelling of the face and tongue,
- Are suffering from a disease with mild to high fever or acute disease. In this case, your doctor will postpone the administration of Dengvaxia until you (or your child) have recovered,
- Have a weakened immune system, for example due to a genetic defect, HIV infection or therapies that affect the immune system (for example, high-dose corticosteroids for 2 weeks or more, or chemotherapy),
- Are pregnant,
- Are breastfeeding.

## ▪ **What should you be aware of before receiving Dengvaxia?**

Tell your doctor before receiving Dengvaxia if you (or your child):

- Have had dengue infection before. If you cannot be sure of whether you have had an infection before, please also inform your doctor. Individuals who have not had dengue infection before should not be vaccinated as an increased risk of hospitalization for dengue and severe dengue has been observed in not previously infected, vaccinated individuals. Previous infection must be confirmed by a test before vaccination.
- Are taking an immunosuppressive treatment (prednisone or equivalent 20 mg or 2 mg/kg body weight for 2 weeks or more). Your doctor will postpone administration of Dengvaxia until at least 4 weeks after you stop taking the treatment.
- Have experienced any health problems after prior administration of any vaccines. Your doctor will carefully consider the benefits and risks of vaccination.

Fainting, sometimes accompanied by falling, can occur (mostly in adolescents) following, or even before, any injection with a needle. Therefore tell the doctor if you (or your child) fainted with a prior injection.

As with any vaccine, some individuals vaccinated with Dengvaxia can still come down with dengue. Personal protection measures against mosquito bites are still recommended after vaccination. Also, there is a need to continue to monitor for dengue symptoms and seek prompt treatment.

▪ **How is Dengvaxia given?**

Dengvaxia is given by your doctor or nurse as an injection underneath the skin (subcutaneous route) in the upper arm.

You (or your child) will receive 3 injections of 0.5 mL each at 6-months intervals. 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. Dengvaxia should be used according to the local vaccination schedule.

▪ **What if you (or your child) missed a scheduled injection?**

Three injections are needed to obtain optimal benefit of the vaccine so it is important not to miss any doses.

If you (or your child) miss a scheduled injection, your doctor will decide when to give the missed injection. It is important that you (or your child) follow the instructions of your doctor regarding return visits for the follow-up injection. If you forget or are not able to go back to your doctor at the scheduled time, ask him/her for advice.

If you have any further questions on the use of this product, ask your doctor.

▪ **What are the common side effects with Dengvaxia?**

Side effects of Dengvaxia include injection site reactions (such as redness, swelling, itchiness and pain), fever, headache, lethargy and muscle ache.

These side effects were of mild to moderate severity and of short duration (0 to 3 days). Onset was typically observed 0 to 3 days after the injection, except for fever which appeared within 14 days after the injection.

Tell your doctor if the side effect bothers you or does not go away.

▪ **What are some of the more serious side effects you may experience?**

If any of these symptoms occur after leaving the place where you (or your child) received the injection, you must consult a doctor IMMEDIATELY:

- difficulty in breathing,
- blueness of the tongue or lips,
- rash,
- swelling of the face or throat,
- low blood pressure causing dizziness or collapse.

When these signs or symptoms occur, they usually develop quickly after the injection is given and while you (or your child) are still in the clinic.

Serious allergic reactions are very rare (may affect up to 1 in 10,000 people), after receiving any vaccine.

Because everyone is different, it is not possible to predict what side effects a person may have. If you (or your child) experience any other side effects not listed in this guide, talk to your doctor.