

**Paediatric population**

The safety and efficacy of COVID-19 Vaccine Moderna in children and adolescents less than 18 years of age have not yet been established. No data are available.

**Elderly population**

No dosage adjustment is required in elderly individuals  $\geq 65$  years of age.

**Method of administration**

The vaccine should be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering the vaccine, see section 4.4.

For instructions regarding thawing, handling and disposal of the vaccine, see section 6.6.

**4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use****Traceability**

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

**Hypersensitivity and anaphylaxis**

Anaphylaxis has been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination. The second dose of the vaccine should not be given to those who have experienced severe allergic reactions (e.g. anaphylaxis, generalised urticaria) to the first dose of COVID-19 Vaccine Moderna.

**Myocarditis and pericarditis**

There have been very rare reports of myocarditis and pericarditis occurring after vaccination with COVID-19 Vaccine Moderna, often in younger men and shortly after the second dose of the vaccine. These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should also seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias.