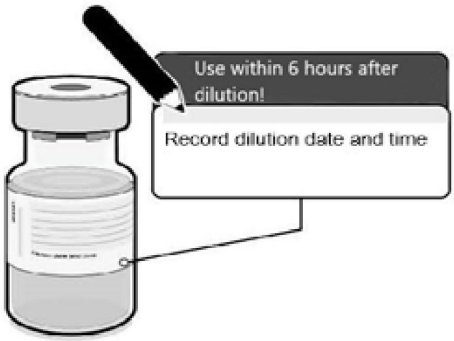
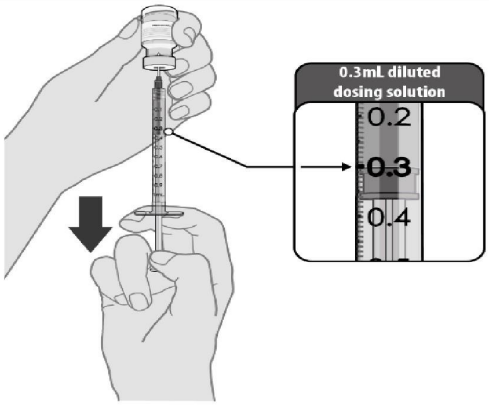
REG 174 INFORMATION FOR UK HEALTHCARE PROFESSIONALS

The diluted vials should be marked with the dilution date and time and stored between 2°C to 25°C. Use as soon as practically possible, and within 6 hours after dilution.	
After dilution, the vial contains 6 doses of 0.3 mL. Withdraw the required 0.3 mL dose of diluted vaccine using a sterile needle and syringe and administer. Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Each dose must contain 0.3 mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. Any unused vaccine should be discarded 6 hours after dilution. The vaccine should not be shipped (transported) by motor vehicle after dilution away from the site of dilution. Any shipping (transportation) by motor vehicle after dilution of the vial is at the risk of the Health Care Professional.	

For instructions on disposal 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

Hypersensitivity and anaphylaxis

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

Close observation for at least 15 minutes is recommended following vaccination. A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of the COVID-19 mRNA Vaccine BNT162b2.

Myocarditis and pericarditis
There have been very rare reports of myocarditis and pericarditis occurring after vaccination with COVID-19 mRNA Vaccine BNT162b2 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.

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.

General recommendations
The administration of COVID-19 mRNA Vaccine BNT162b2 should be postponed in individuals suffering from acute severe febrile illness. The presence of a minor infection and/or low-grade fever should not delay vaccination.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection, should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. No data are available about concomitant use of immunosuppressants.

As with any vaccine, vaccination with COVID-19 mRNA Vaccine BNT162b2 may not protect all vaccine recipients.

No data are available on the use of COVID-19 mRNA Vaccine BNT162b2 in persons that have previously received a full or partial vaccine series with another COVID-19 vaccine.

Excipient information
This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'.
This vaccine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concomitant administration of COVID-19 mRNA Vaccine BNT162b2 with other vaccines has not been studied (see section 5.1).

Do not mix COVID-19 mRNA Vaccine BNT162b2 with other vaccines/products in the same syringe.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is limited experience with use of the COVID-19 mRNA Vaccine BNT162b2 in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). Administration of