**Individual patient assessment to assist the Patient Specific Direction (PSD) for the administration of Comirnaty® 3 (THREE) concentrate vaccine to 6-month to 4-year-olds in a clinical risk group by suitably trained vaccinators.**

|  |  |  |  |
| --- | --- | --- | --- |
| **First Name(s)** |  | **Date of birth** |  |
| **Surname** |  | **NHS No.** |  |
| **Home address** |  | | |
| **Postcode** |  | **Registered Practice** |  |
| **Home Tel No** |  | **Mobile No** |  |
| **Ethnicity** |  | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Assessors Name or ID Number** |  | **ID No** |  | | |  | | |
| **Please ask the parent or carer of the child presenting for vaccination these questions and record that they have received appropriate counselling as to the purpose of the vaccine and side effects** | | | | | | | | |
| **Is the child aged between 6 months to 4 years?** | | | | **No** |  | | Yes\* |  |
| **Does the child meet the criteria of a clinical at risk group as listed in table 4 in the Green Book Chapter 14a? (also see table below for reference).**  *JCVI does not currently advise COVID-19 vaccination of children aged 6 months to 4 years who are not in a clinical risk group* | | | | **No** |  | | Yes\* |  |
| **Has the recipient received a previous dose of a COVID vaccine?** | | | | **No** |  | | Yes\* |  |
| **If yes, was their last dose at least 8**  **weeks ago?** | | | | **No** |  | | Yes\* |  |
| **Is the recipient currently unwell with fever?** *(Note: the presence of a minor infection is not a contraindication for vaccination)* | | | | **No** |  | | Yes\* |  |
| **Has the recipient ever had any serious allergic reaction?** | | | | **No** |  | | Yes\* |  |
| **Has the recipient ever been prescribed an adrenaline autoinjector such as an epipen?** | | | | **No** |  | | Yes\* |  |
| **Does the recipient have a hypersensitivity to the active substance or to any of the excipients?**  *Note: Comirnaty 3 (THREE) vaccine contains polyethylene glycol (PEG) 2000, refer to the product’s* [*SPmC*](https://www.medicines.org.uk/emc/product/14405) *for a full list of excipients.* | | | | **No** |  | | Yes\* |  |
| **Has the recipient experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination?** | | | | **No** |  | | Yes\* |  |
| **# Is the recipient currently in or been in a trial of a potential coronavirus vaccine?** | | | | **No** |  | | Yes\* |  |
| **Is the recipient taking anticoagulant medication, or do they have a bleeding/coagulation disorder?\*\*** | | | | **No** |  | | Yes\* |  |

**\*If any of the ‘non- bolded’ answer boxes are ticked, then a further review by the prescriber must take place. For Individuals with a prior allergic reaction to any component (excipient) of the COVID-19 vaccine e.g. polyethylene glycol or unestablished history of anaphylaxis appropriate advice should be sought from the relevant specialist**.

**If you or the person presenting for vaccination are uncertain as to the response or counselling required, they should seek further advice. See later for specific advice.**

**\*\*See below notes for prescriber/clinician section**

**Table 4: Clinical risk groups for individuals aged under 16 years**

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Description automatically generated

1. Poorly controlled asthma is defined as: - ≥2 courses of oral corticosteroids in the preceding 24 months OR - on maintenance oral corticosteroids OR - ≥1 hospital admission for asthma in the preceding 24 months <https://www.brit-thoracic.org.uk/covid-19/covid-19-information-for-the-respiratory-community/#jcvi-advice-on-covid-19-vaccination-for-children-aged-12-15-years-in-clinical-at-risk-groups>)

**Reference:** [The Green book, Chapter 14a – Covid -19](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1153300/Greenbook-chapter-14a-26April2023.pdf), accessed 13/05/2023

**Patient Specific Direction (PSD) for the administration of Comirnaty® 3 (THREE) Concentrate vaccine to 6-month to 4-year-olds in a clinical risk group by suitably trained vaccinators**

**Date of PSD: DD/MM/2023**

**The patient named below is eligible to receive:**

**Comirnaty THREE (3 micrograms/dose) concentrate for dispersion for injection 0.2mLs Intra-Muscular (IM) Injection**

**in accordance with Public Health England Immunisation against infectious disease (Green Book Guide) and JCVI recommendations for the purpose of protection against COVID-19.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Patient** |  | **Date of Birth** |  |
| **Address** |  | **NHS number:** | |

**ONE DOSE** of Comirnaty® 3 (THREE) COVID-19 vaccine is 0.2 mL containing 3 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles) administered by Intra-Muscular (IM) injection.

The Comirnaty ® THREE (3 micrograms/dose) COVID-19 vaccine must be diluted prior to administration in line with the Summary of Product Characteristics.

**Vaccination Centre / PCN / Hospital Hub Name and Address**

|  |  |  |
| --- | --- | --- |
|  | | |
| **Name of Prescriber** | **Signature of Prescriber** | **Date and Registration Number** |
|  |  | **DD/MM/2023** |

**This PSD will expire within 7 days of prescriber’s signature**

|  |  |  |
| --- | --- | --- |
| **Name of clinician drawing up the vaccine** | **Signature of registered clinician** | **Date & Time of drawing up** |
|  |  |  |
| **Name of Vaccine Administrator (i.e. person giving the vaccine)** | **Signature of Administrator** | **Date & Time of Vaccination** |
|  |  |  |
| **Vaccination given:** | **Batch Number:** | **Expiry:** |
| **Is this the recipients first or second dose** (tick as appropriate) | **Dose 1** | **Dose 2**  (Confirm an 8-week interval has elapsed between doses) |
| **Is this the recipients third primary dose** | **Dose 3**  (Confirm a minimum of three months after second or subsequent dose) | |
| **Vaccination site:** | **Left Arm**  **Left thigh** | **Right Arm**  **Right thigh** |
| **Patient section**  **Signature of parent/carer:** | | |

**Notes for Prescriber/Clinician**

Comirnaty 3 micrograms/dose concentrate for dispersion for injection is not intended for individuals older than 5 years of age.

The prescriber should be aware of the MHRA Conditions of authorisation (**Black triangle▼**) and the vaccine’s contraindications: <https://www.medicines.org.uk/emc/product/14405>

In infants from 6 to less than 12 months of age, the recommended injection site is the anterolateral aspect of the thigh. In individuals 1 year of age and older, the recommended injection site is the anterolateral aspect of the thigh or the deltoid muscle.

The infant formulation Comirnaty® THREE (3micrograms/dose) is supplied in a multidose vial with a maroon cap, with each vial containing 10 doses of 0.2 mL injection volume (after dilution with 2.2 mL of saline). The primary course is approved to be administered in three doses, with the second dose a minimum of 21 days after the first and the third dose after a further eight weeks (see above). However current JCVI advice is that **two doses should be given eight weeks apart**.

Allergy to any excipient is possible, but polyethylene glycol (PEG) is of particular importance.  See [the Green Book Chapter 14a: COVID-19](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1102459/Greenbook-chapter-14a-4September22.pdf) for details on how to manage individuals with a history of allergy.

Children below six years of age, including those who commenced immunisation with the 3-microgram infant dose before turning five, may commence and complete primary vaccination with the 3 microgram infant dose of Pfizer BioNTech if that is the only vaccine readily available in the clinic.

There is an increased risk of myocarditis and pericarditis following vaccination with Comirnaty. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination*.*

*#* Any person who has been involved in a coronavirus trial should be advised to contact the trial organisers to seek guidance on whether or when vaccination should take place*.*

\*\*Taking anticoagulants or a bleeding disorder is not a contraindication to intramuscular injections, but the recipient needs to be aware that they may have increased bruising and be advised to apply pressure. Those with bleeding disorders may wish to time vaccination to occur shortly after appropriate therapies. Please also refer to the relevant chapter in the Green Book – Chapter 14a. <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

**Other Details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Consent given by:** | **Parent** | **Relative** | **Carer** |
| **Aftercare advice given to patient/carer:**  **Try to review the ‘Red book’ (Personal Child Health Record) and highlight the importance of being up to date with routine vaccinations** | **Yes**  **Yes**  *Does the parent/relative or carer have any questions:* | | |