

Healthcare Provider or Authorised Dispenser Information

[PRODUCT for INTENDED USE]

An emergency has been declared by the Ministry of Health.

[INCLUDE A BRIEF DESCRIPTION (1-2 sentences) OF THE EMERGENCY].

The MCA has authorised the emergency use of [PRODUCT] for a use [IDENTIFY THE INTENDED USE] that has not yet obtained MCA marketing authorisation (registration) by usual MCA processes. This authorisation will terminate on [DATE 1 YEAR FROM THE DATE OF DECLARATION], or when the emergency has ceased to exist, whichever is earlier.

The information in this form is the minimum information necessary to inform you of the significant known and potential risks and benefits of emergency use of [PRODUCT].

The significant known and potential risks and benefits of emergency use of [PRODUCT] are: [LIST]. The extent to which such risks and benefits are unknown is [EXPLAIN].

The available alternatives to [PRODUCT] are: [LIST]. The risks and benefits of [ALTERNATIVES] are: [LIST]. [If there is no alternative, provide an explanation of outcomes of exposure or of any special public health measures (e.g. quarantine or monitoring) that an individual who does not receive the EUA product may face.]

[INCLUDE NAME, ADDRESS, AND TELEPHONE NUMBER FOR MANUFACTURER.]

As the healthcare provider or authorised dispenser or pharmacist administering [PRODUCT], please communicate the significant known and potential risks and benefits, and the extent to which such risks and benefits are unknown, to the recipient of [PRODUCT].

Please inform the recipient that he or she has the option to accept or refuse administration of [PRODUCT], and of the consequences of refusing administration. Please inform the recipient of any available alternatives to [PRODUCT], and of their risks and benefits. Please provide the "Recipients Information" to the recipient of [PRODUCT].

If providing this information before administration would delay the administration of [PRODUCT] to a degree that would endanger the lives of exposed or affected individuals, the information must be provided to the recipient as soon as practicable after [PRODUCT] is administered.

MCA also recommends that E.U.A applicants include the following additional information in the "Conditions of Use" document for Healthcare Providers or Authorised Dispensers or Pharmacist if it is available.

Instructions for Use by the Healthcare Provider or Authorised Dispensers

How to administer the product (including dose, route of intake or infusion, how long to use the product, how to take care of the infusion site), how to store the product, how it is supplied/forms that it comes in, how to constitute.

Known major interactions with other products or substances, including drug interactions, cross reactivity for intravenous drugs.

Known efficacy information or performance characteristics for IVDs

Contraindications or warnings

Adverse events. Significant known adverse event information (e.g. what are the significant known side effects? Under what conditions should the recipient stop taking product?), instructions for follow up in case of an adverse event, how to report an adverse event, what to do in case of an adverse event (stop using the product? seek treatment?), whom to contact for professional advice if an adverse event occurs or if the product does not work. Healthcare providers or authorised dispensers also shall report adverse events to the MCA.

Alternatives. If other products may treat or prevent the same or closely related condition for [INTENDED USE], this information should be stated. If available, the relative or expected safety and effectiveness of the alternative should be provided, particularly for use in different populations or settings. Such information may include:

- When an alternative product may be more appropriate, e.g. in the treatment of the pregnant women, infants and children, and immunocompromised individuals, or other special populations.
- For preventive treatments, the time needed for [PRODUCT] to be administered in advance of the exposure to be effective, and alternatives that may be more effective if that time is exceeded.

Significant known and potential risks and benefits may include relevant information about the manufacturer (e.g. a waiver of Good Manufacturing Practices compliance), if known.

Consequences of not taking/using [PRODUCT], including possible health effects and quarantine, and of stopping the use of [PRODUCT] against the recommendation of the healthcare provider.

New findings. A statement about the fact that any significant new findings observed during or after the course of widespread use will be made available.

Approved products. For approved products being used for unapproved indications, the "Conditions of Use" document also may include critical elements from the package insert.

Contacts. Whom to contact if you have any questions or concerns (other than an adverse event report) about the product.