Northern Territory of Australia

Medicines, Poisons and Therapeutic Goods Act 2012

Vaccine for Human Therapeutic Use – Japanese Encephalitis SSTP

Revocation and Approval

I, Christine Maree Connors, Acting Chief Health Officer:

(a) under section 254(5) of the *Medicines, Poisons and Therapeutic Goods Act 2012, (**the Act**),* revoke the instrument titled "Declarations and Approvals – Japanese Encephalitis Vaccine" dated 26 September 2022 and published in *Gazette* No.s48 of 26 September 2022; and

(b) under section 254(1) of the Act, approve each Scheduled substance treatment protocol specified in Schedule A;

(c) under section 254(3) of the Act, state that each Schedule substance treatment protocol specified in Schedule A remains in effect until 02 August 2024

Dated **13/04/2023**

Acting Chief Health Officer

Schedule A

Title	Publication Date	Author
Imojev® for Japanese Encephalitis Vaccine Scheduled Substance Treatment Protocol (SSTP)	02/08/2022	Center for Disease Control, Northern Territory Government, Department of Health
JESPECT® for Japanese Encephalitis Vaccine Scheduled Substance Treatment Protocol (SSTP)	02/08/2022	Center for Disease Control, Northern Territory Government, Department of Health

Imojev® for Japanese Encephalitis Vaccine Scheduled Substance Treatment Protocol (SSTP)

Areas Applicable	NT Wide
Health Professionals authorised by this SSTP	Nurses Midwives Aboriginal and Torres Strait Islander Health Practitioners Pharmacists
Scheduled Substance(s)	Imojev® Vaccine (live attenuated JE vaccine)
Indication	People at risk of Japanese Encephalitis who are working or living in areas suspected to be a risk of transmission of JE virus
Contraindications and/or Exclusions*	Imojev® is contraindicated in people who are: • Immunocompromised • Children under 9 months • Pregnant women or women planning pregnancy • Breastfeeding women • People who have received immunoglobulin or blood products within the last 3 months • People who have had anaphylaxis after a previous dose of any JE vaccine or to any component of a JE vaccine • People with an acute febrile illness
Dose and Route*	0.5mL reconstituted dose
Dose Frequency*	Single dose
Administration*	Subcutaneous injection (prepare as per package insert) For infants aged < 12 months the preferred injection site is the anterolateral thigh. For individuals aged >12 months the preferred injection site is the deltoid muscle of the upper arm.
Drug Interactions*	Imojev® is a live vaccine and so can be given at the same time as other live vaccines OR at least 28 days apart. If given at the same time it needs to be in separate limbs.
Monitoring requirements*	Observe for 15 minutes post vaccination delivery for adverse reaction and if an adverse events occurs an "'Adverse event following vaccination' form must be completed and sent to the Centres for Disease Control (CDC)

NORTHERN TERRITORY GOVERNMENT

<table>
<tr><td>Health Professionals Accreditation Requirements</td><td colspan="3">Nurses and Midwives:
Be registered with the Nursing and Midwifery Board of Australia with no conditions, undertakings or notations which may limit delivery of clinical services directly to patients
Aboriginal Health Practitioners:
Be registered with the Aboriginal and Torres Strait Islander Health Practice Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients
Pharmacists
Be registered with the Pharmacy Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients
All health professionals
Must have completed nationally recognised immunisation training in a program that meets the “National Immunisation Education Framework for Health Professionals 2017” and is nationally accredited and;
Must holds a current first aid certificate (to be updated every three years) and;
Must hold a current cardiopulmonary resuscitation certificate (to be updated annually).</td></tr>
<tr><td>Documentation
(including necessary information to the patient)</td><td colspan="3">JE vaccines should be documented in the Australian Immunisation Register and the client’s electronic health record.</td></tr>
<tr><td>Related Documents</td><td colspan="3">Japanese Encephalitis - The Australian Immunisation Handbook (health.gov.au) https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/japenese-encephalitis

ATAI statement ATAGI clinical guidance on Japanese encephalitis virus vaccines | Australian Government Department of Health
Product Information TGA eBS – Product and Consumer Medicine Information</td></tr>
<tr><td rowspan="2">Chief Health Officer</td><td>Signature</td><td>Name</td><td>Date</td></tr>
<tr><td>EDOC2022/329118</td><td>Dr Charles Pain</td><td>02/08/2022</td></tr>
<tr><td>Date for Review</td><td colspan="3">This SSTP is in effect from time of publishing on Agency website until 02/08/2024</td></tr>
<tr><td colspan="4">References:
* The drug information provided is to act as a guide only, for further information reference should be made to the full manufacturer’s product info and other reliable sources of medicines information. If contraindications or interactions are present refer to medical officer before administration</td></tr>
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JESPECT® for Japanese Encephalitis Vaccine Scheduled Substance Treatment Protocol (SSTP)

Areas Applicable	NT Wide	
Health Professionals authorised by this SSTP	Nurses Midwives Aboriginal and Torres Strait Islander Health Practitioners Pharmacists	
Scheduled Substance(s)	JESPECT®/ IXIARO® vaccine (JE vaccine)	
Indication	People at risk of Japanese Encephalitis who are working or living in areas suspected to be a risk of transmission of JE virus who are unsuitable for Imojev®	
Contraindications and/or Exclusions*	JESPECT®/ IXIARO® is contraindicated in: • Children under 2 months • People who have had anaphylaxis after a previous dose of any JE vaccine or to any component of a JE vaccine • People with an acute febrile illness	
Dose and Route*	Infants aged ≥2 months to <3 years; 0.25mL	Children aged ≥ 3 years and adults; 0.5mL
Dose Frequency*	2 doses at least 28 days apart	
Administration*	Intramuscular injection For infants aged < 12 months the preferred injection site is the anterolateral thigh. For individuals aged >12 months the preferred injection site is the deltoid muscle of the upper arm.	
Drug Interactions*	JESPECT®/ IXIARO® can be given at the same time as Hepatitis A, Meningococcal ACWY and Rabies vaccines as long as separate syringes are used and doses are given at least 2.5cm apart.	
Monitoring requirements*	Observe for 15 minutes post vaccination delivery for adverse reaction and if an adverse event occurs an 'Adverse event following vaccination' form must be completed and sent the Centres for Disease Control (CDC).	

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