Amir PB
5/3 15

RANCANGAN INFORMASI PRODUK

IMOJEV®

Powder and diluent* for suspension for injection

ACC

Japanese encephalitis vaccine (live, attenuated)

***0.4% sodium chloride solution (IMOJEV®)**
***0.9% sodium chloride solution (IMOJEV® MD)**

COMPOSITION

After reconstitution, one dose (0.5 mL) contains:

Live, attenuated, recombinant Japanese encephalitis virus*: 4.0 - 5.8 log PFU**
* Propagated in Vero cells
** Plaque Forming Unit

List of excipients

Powder
Mannitol, Lactose monohydrate, Glutamic acid, Potassium hydroxide, Histidine, Human Serum Albumin

Diluent
Sodium chloride, Water for injections

No adjuvant or antimicrobial preservative is added

PHARMACEUTICAL FORM

Powder and diluent for suspension for injection

The powder is a white to creamy white homogeneous cake which might be retracted from the sides of the vial.
The diluent is a clear solution.
After reconstitution, IMOJEV® is a colourless to amber suspension.

THERAPEUTIC INDICATION

IMOJEV® is indicated for prophylaxis of Japanese encephalitis caused by the Japanese encephalitis virus, in subjects from 12 months of age and over.

POSOLOGY AND ADMINISTRATION

Posology

Primary Vaccination:

Subjects 12 months of age and over: a 0.5 mL single injection of the reconstituted vaccine.

Booster

- Paediatric population

  If l a long term protection* is required, a booster dose of IMOJEV®, should be given after primary vaccination. The booster dose should be given preferably 12 months after primary vaccination and can be given up to 24 months after primary vaccination.

  IMOJEV® can also be given as a booster vaccination in children who were previously given an inactivated Japanese encephalitis vaccine for primary vaccination, in accordance with the recommended timing for the booster of the inactivated Japanese encephalitis vaccine.

  **Immunity is maintained at a high level at least 3 years after the booster dose.*

- Adult population:

  The need for and timing of a possible booster dose have not yet been determined.

Method of administration

Once the freeze-dried vaccine has been completely reconstituted using the diluent provided (*see section Special Precautions for Disposal and Other Handling)*, it is administered via the subcutaneous route.

In subjects 2 years of age and over, the recommended injection site is the deltoid region of the upper arm.

In subjects between 12 and 24 months of age, the recommended injection site is the anterolateral aspect of the thigh or the deltoid region.

Do not administer by intravascular injection

IMOJEV® must not be mixed with any other injectable vaccine(s) or medicinal product(s)

Contraindication

IMOJEV® should not be administered to anyone with a history of severe allergic reaction to any component of the vaccine or after previous administration of the vaccine or a vaccine containing the same components or constituents.

Vaccination must be postponed in case of febrile or acute disease.

Congenital or acquired immune deficiency impairing cellular immunity, including immunosuppressive therapies such as chemotherapy, high doses of systemic corticosteroids given generally for 14 days or more (see sections 4.4 and 4.5).

IMOJEV® must not be administrated to persons with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function.

Pregnancy *(see section Pregnancy)*.

Lactation *(see section Lactation)*.

Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following administration of the vaccine.

For patients following a treatment with high doses of systemic corticosteroids given for 14 days or more, it is advisable to wait for at least one month or more following the interruption of therapy before carrying out the vaccination until immune function has recovered.

Do not administer by intravascular injection.

Interaction with other medicinal products and other forms of interaction

IMOJEV® may be administered to adults at the same time as yellow fever vaccine using separate syringes, and into separate limbs

In the case of immunosuppressive therapy or corticosteroid therapy, *see sections Contraindication and Special warnings and Precautions for use*

Administering the vaccine in subjects who have previously received immunoglobulins:
In order to avoid any neutralisation of the attenuated viruses contained in the vaccine, vaccination must generally not be performed within 6 weeks, and preferably not within 3 months of injection of immunoglobulins or blood products containing immunoglobulins, such as blood or plasma.

Pregnancy and lactation

No animal reproduction studies have been conducted with IMOJEV® (*see section Preclinical Safety Data*).
As with all live attenuated vaccines, pregnancy constitutes a contra-indication *(see section Posology and Administration)*.

It is not known whether this vaccine is excreted in human milk.
IMOJEV® vaccination is contraindicated in breastfeeding women (*see section Contraindication*).

Effects on the ability to drive and use machines

No studies on the effects on the ability to drive or use machines have been performed.

Undesirable effects

Data from clinical trials
Data in adult population

The safety of IMOJEV® has been assessed in 8 randomised clinical trials in subjects over 18 years of age. During the development in the adult population, approximately 2,500 subjects received an injection of IMOJEV®.

Safety evaluation was performed for all subjects during the first 4 weeks following vaccination and serious adverse reactions were collected during at least six months of follow-up after a single dose of IMOJEV®.

The most frequently reported systemic reactions after the administration of IMOJEV® vaccine were headache, fatigue, malaise and myalgia. All these reactions were as frequently reported as after the administration of the inactivated Japanese encephalitis comparator vaccine or a placebo.

The most frequently reported reaction at the injection site after the administration of IMOJEV® vaccine was injection site pain. All the injection site reactions were less frequently reported than after the administration of the inactivated Japanese encephalitis comparator vaccine and as frequently reported as after the administration of a placebo.

Local and systemic reactions are ranked within each system organ class, under headings of frequency, using the following convention [Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000), including isolated reports].

The following possibly related Adverse Events were reported during clinical trials within 30 days after vaccination:

General disorders and administration site conditions:

- Very common: Fatigue, malaise, injection site pain
- Common : Feeling hot, chills, injection site erythema, injection site pruritus, injection site swelling, injection site bruising
- Uncommon : Pyrexia

Nervous system disorders:

- Very common: Headache
- Common : Dizziness

Musculoskeletal and connective tissue disorders:

- Very common: Myalgia
- Common : Arthralgia

Gastrointestinal disorders:

- Common : Diarrhoea , nausea, abdominal pain, vomiting

Respiratory, thoracic and mediastinal disorders:

- Common : Pharyngolaryngeal pain, dyspnea, rhinorrhoea, cough, wheezing, nasal congestion

Skin and subcutaneous tissue disorders:

- Common : Rash

Infections and infestations:

- Rare : Viral infections

Data in paediatric populations

The safety of IMOJEV® has been assessed in 2 randomised clinical trials in subjects between 12 months and 5 years of age. During the development in paediatric populations, approximately 1,400 subjects (100 children and 1,300 toddlers) received an injection of IMOJEV®.

Safety evaluation was performed for all subjects during the first 4 weeks following vaccination and serious adverse reactions were collected during at least six months of follow-up after a single dose of IMOJEV®.

The most frequently reported systemic reactions were malaise, fever, headache, and myalgia in children (2 to 5 years) previously immunized with a two-dose primary vaccination with an inactivated Japanese encephalitis vaccine; and fever, appetite lost and irritability in toddlers (12 to 24 months) not previously immunized with a Japanese encephalitis vaccine

The most frequently reported reactions at the injection site after the administration of IMOJEV® vaccine was injection site pain/tenderness and injection site erythema.

These adverse events observed during paediatric clinical trials were generally of mild intensity and of short duration. The onset of systemic reactions was generally seen within 3 days after immunisation.

Local and systemic reactions are ranked within each system organ class, under headings of frequency, using the following convention [Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), including isolated reports].

The following related Adverse Events were reported during clinical trials within 28 days after vaccination:

General disorders and administration site conditions:

- Very common: Pyrexia, malaise, irritability, injection site pain/tenderness, injection site erythema
- Common : Injection site swelling
- Uncommon : Injection site reactions (induration, pruritus, bruising, haematoma, bleeding)

Nervous system disorders:

- Very common: Headache, somnolence

Musculoskeletal and connective tissue disorders:

- Very common: Myalgia

Gastrointestinal disorders:

- Very common: Vomiting

Metabolism and nutrition disorders

- Very common: Appetite loss

Skin and subcutaneous tissue disorders:

- Rare: Rash, urticaria, maculo-papular rash

Psychiatric disorders:

- *Very common:* Abnormal crying

Infections and infestations:

- Rare : Upper respiratory tract infection, viral infections

The safety of IMOJEV® has also been assessed in Phase III trial in 390 subjects between 36 and 42 months of age (45 out of the 390 received a single dose of IMOJEV®, and 345 out of the 390 received a second dose (booster dose) of IMOJEV® 2 years after the first dose. The safety profile presented no clinically relevant difference with the above-described safety profile

Data from post-marketing experience
There are no safety data from post-marketing experience at this time.

Overdose
Not documented.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Mechanism of action
The vaccine is a live attenuated virus. Following administration, the virus replicates locally and elicits neutralising antibodies and cell-mediated immune responses that are specific to the Japanese encephalitis virus. Available results indicate that protection is mainly mediated by neutralising antibodies.
In nonclinical studies, all animals that received a single dose of the vaccine developed specific neutralising antibodies against Japanese encephalitis virus and were protected against infection by a virulent Japanese encephalitis virus experimental challenge.

Immunogenicity

Passive antibody transfer results in a small animal model indicate that protection is mediated by neutralising antibodies and that the threshold for protection is a plaque reduction neutralisation titer of 1:10.

Immunogenicity data in adult population

A single dose administration of IMOJEV® is as immunogenic as a three-dose regimen of an inactivated Japanese encephalitis comparator vaccine administered in adults 18 years of age and over.

A seroprotective level of antibodies is generally reached 14 days after vaccination.

In a randomised comparative phase III trial, 410 subjects over 18 years of age received a single dose of not less than 4.0 log PFU/dose of 0.5 mL of IMOJEV® and 410 subjects over 18 years of age received a three-dose regimen of 1 mL of an inactivated Japanese encephalitis comparator vaccine.

Thirty days after vaccination, the seroprotection rates for the subjects who received IMOJEV® were more than 99% when measured against the homologous virus strain. These results are non-inferior to those observed after the three-dose regimen of the inactivated Japanese encephalitis comparator vaccine.

Fourteen days after a single dose of IMOJEV®, approximately 93% of the vaccinees showed seroprotective levels of neutralising antibodies.

In a long-term follow-up assessment in a randomised control phase II trial, 97.6% (95% CI, 93.3; 98.8) of subjects showed seroprotective levels six months after a single administration of IMOJEV®.

"Long-term immunogenicity data up month 60 are presented as Kaplan-Meier estimates. The probability of being still seroprotected 60 months after vaccination for those who were seroprotected at six months is 86.8%."

Immunogenicity data in paediatric populations

- Primary Vaccination

  A seroprotective level of antibodies is generally reached 28 days after vaccination

  A single dose administration of IMOJEV® in 2 randomised trials in 1,231 toddlers (12 to 24 months) not previously immunized with a Japanese encephalitis vaccine shows that approximately 95% of subjects seroconverted and are seroprotected (neutralizing antibody level above the threshold of protection) after 28 days.

  The persistence of seroprotection was assessed in a Phase II and a Phase III trials in toddlers (12 to 24 months)

  In the Phase II trial, approximately 75% of toddlers who did not receive any Japanese encephalitis vaccine before the single dose administration of IMOJEV® were shown to till have seroprotective antibody level 3 years after the vaccination (N = 157).

  Table 1 shows the immune response up to 3 years after vaccination with a single dose of IMOJEV®

Table 1 : Immune Response up to 3 years after a Single-Dose of IMOJEV® in Toddlers (12 to 24 Months) Not Previously Immunised with a JE Vaccine

	Seroprotection* (≥10 I/dil) % (95% CI)	GMT* I/dil (95% CI)
28 days after a single dose of IMOJEV® (N=194)	96.4 (92.7; 98.5) †	295.8 (231.6; 377.9) †
6 months after a single dose of IMOJEV® (N = 197)	86.8 (81.3; 91.2) †	69.5 (55.9; 86.4) †
1 year after a single dose of IMOJEV® (N = 185)	82.2 (75.9; 87.4) ‡	58.2 (46.2; 73.3) ‡
2 years after a single dose of IMOJEV® (N = 172)	80.2 (73.5; 85.9) ‡	70.3 (54.3; 91.1) ‡
3 years after a single dose of IMOJEV® (N =157)	75.2 (67.6; 81.7) ‡	60.6 (45.4; 80.7) ‡

* Based on homologous virus strain

† Full analysis set

‡ Sensitivity analysis in the Full analysis set to avoid a bias in the antibody measurement over time due to potential discontinuations of subjects with antibody titres below the threshold of protection

In the Phase III trial, approximately 86% of toddlers who did not receive any Japan encephalitis vaccine before the single dose administration of IMOJEV® were shown to have seroprotective antibody levels 2 years after the vaccination (N=574). All the todd included in this trial with serological data available 28 days after the vaccination w seroprotected at this timepoint

Table 2 shows the immune response against the homologous virus, up to 2 years a vaccination with a single dose of IMOJEV®

Table 2 : Immune Response up to 2 Years after a Single-Dose of IMOJEV® in Toddlers (12 to 24 Months) Previously Immunised with a JE Vaccine and Seroprotected 28 days after the Single-Dose

	Seroprotection (≥10 I/dil) %* *(95% CI)*	*GMT** *I/dil* *(95% CI)*
28 days after a single dose of IMOJEV® (N=580)	100.0 (9.4; 100.0) †	253 (225; 284) ‡
1 year after a single dose of IMOJEV® (N =586)	88.2 (85.3; 90.7) †	77.2 (67.7; 88.0) †
2 years after a single dose of IMOJEV® (N = 574)	85.9 (82.8; 88.6) ‡	71.4 (62.7; 81.3) ‡

* Based on homologous virus strain

† Full analysis set (main analysis)

‡ Sensitivity analysis to avoid a bias in the antibody measurement over time due to the potential discontinuations of subjects with antibody titres below the threshold of protection

- Booster
  - Booster dose of IMOJEV® after primary vaccination with IMOJEV®

    In a Phase III trial, a second dose (booster dose) of IMOJEV® was administered in children (36 to 42 months) (N = 340) 24 months after primary vaccination with IMOJEV®. A control group of children (36 to 42 months) (N = 39) who never received a Japanese encephalitis vaccine, received IMOJEV® for the first time to characterize the primary response to IMOJEV®.

    The Geometric Mean Titer (GMT) increased by nearly 6 fold from Day 0 to Day 7 after the administration of IMOJEV® to subjects previously vaccinated. By comparison, the GMT did not increase the control group, thus demonstrating an anamnestic response in the booster group. The GMT increased by nearly 57 fold from Day 0 to Day 28 in the booster group.

    100% of children previously vaccinated with IMOJEV® showed seroprotective antibody levels 28 days after the administration of the booster dose.

    Table 3 shows the immune response against the homologous virus strain, 7 and 28 days after administration of a booster dose of IMOJEV®

Table 3 : Immune Response to a Booster Dose of IMOJEV given to Children (36 to 42 Months) 24 Months after a Single-Dose of IMOJEV vs. Control Children (36 to 42 Months) receiving a Single Dose of IMOJEV®

Group	Parameter	D0	D7	D28
IMOJEV® primary vaccinated toddlers (N = 340)	Seroprotection* (≥10 I/dil) % [95% CI]	80.3 [75.5; 84.4]	96.2 [93.6; 97.9]	100.0 [98.9; 100.0]
	GMT* I/dil (ratio Dx/D0) [95% CI]	39.4 [33.7; 46.0]	231 (5.87) [191; 279]	2.242 (57.0) [1.913; 2.628]
Japanese encephalitis vaccine naïve control group (N=39)	Seroprotection* (≥10 I/dil) % [95% CI]	0.0 [0.0; 9.0]	15.4 [5.9; 30.5]	89.7 [75.8; 97.1]
	GMT* I/dil (ratio Dx/D0) [95% CI]	5.00 [5.00; 5.00]	6.41 (1.28) [5.11; 8.05]	178 (35.6) [99.7; 318]

* Based on homologous virus strain

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In the long-term follow –up assessment of the phase III trial, nearly all children (99.4%) who received the booster dose of IMOJEV® 24 months after primary vaccination were shown to still have seroprotective antibody levels 1 year after the vaccination.
Table 4 shows the immune response 28 days and 1 year after vaccination with a booster dose of IMOJEV®

Table 4. Immune Response 28 days and 1 year after the Administration of a Booster Dose of IMOJEV in Children (36 to 42 Months) 24 Months after a Single-Dose of IMOJEV®

	Seroprotection (≥10 I/dil) % (95% CI)*	*GMT* (I/dil) (95% CI)*
28 days after a booster dose of IMOJEV® (N=345)	100.0 [98.9;100.0]	2.259 (1.930; 2.645)
1 year after a single dose of IMOJEV® (N =339)	99.4 (97.9; 99.9)	596 (502; 708)

* Based on homologous virus strain

- Booster vaccination with IMOJEV® after the administration of an inactivated JE vaccine as a primary immunization.

In a Phase II trial, IMOJEV® was administered to children (2 to 5 years) (N = 97) 6 to 38 months after a two-dose primary vaccination with an inactivated Japanese encephalitis vaccine (mouse brain-derived Japanese encephalitis vaccine)

The GMP increased by nearly 59 fold from Day 0 to Day 28. Approximately 93% of subjects seroconverted and they were all seroprotected (titer above a threshold considered as protective) 28 days after the administration of IMOJEV®.

Table 5 shows the immune response 28 days after the administration of a booster dose of IMOJEV® after a primary vaccination with an inactivated JE vaccine.

Table 5 : Immune Response 28 Days After the Administration of a Booster Dose of IMOJEV® in Children (2 to 5 Years) after a Two-dose Primary Vaccination with an Inactivated JE Vaccine

Parameter	D0	D28
Seroprotection* † % [95% CI]	85.6 [77.0;91.9]	100.0 [96.3; 100.0]
Seroconversion* ‡ % [95% CI]	-	92.8 [85.7; 97.0]
GMT* I/dil (ratio Dx/D0) [95% CI]	44.8 [33.8; 59.4]	2.634 (58.7) [1.928; 3.600]

* Based on homologous virus strain

† Seroprotection refers to neutralizing antibody titre above the threshold of protection

‡ Seroconversion refers to

- In individuals previously immunized and who are seronegative at baseline: neutralizing antibody titre above the threshold of protection after vaccination with IMOJEV®
- In individuals who are seropositive at baseline : at least a fourfold rise in neutralizing antibody titre after vaccination with IMOJEV®

In the long-term follow up assessment of the phase II trial, nearly all children (97.5%) who received the booster dose of IMOJEV® 6 to 38 months after the two-dose primary vaccination with the inactivated Japanese encephalitis vaccine were shown to still have seroprotective antibody levels 3 years after the vaccination

Table 6 shows the immune response up to 3 years after the administration of a booster dose of IMOJEV® after a primary vaccination with an inactivated JE vaccine

Table 6 : Immune Response up to 3 Years after the Administration of a Booster Dose of IMOJEV® in Children (2 to 5 Years) after a Two-dose Primary Vaccination with an Inactivated JE Vaccine

	Seroprotection (≥10 I/dil)* *%* *(95% CI)*	*GMT** *I/dil* *(95% CI)*
6 months after the administration of IMOJEV® (N = 97)	100.0 (96.3; 100.0) †	1,055.4 (771.4; 1,444.0) †
1 year after the administration of IMOJEV® (N = 93)	96.8 (90.9; 99.3) ‡	454 (327; 632) ‡
2 years after the administration of IMOJEV® (N = 84)	97.6 (91.7; 99.7) ‡	521 (364; 744) ‡
3 years after the administration of IMOJEV® (N = 78)	97.5 (91.3; 99.7) ‡	411 (298; 569) ‡

* Based on homologous virus strain
† Full analysis set
‡ Sensitivity analysis in the Full analysis set to avoid a bias in the antibody measurement over time due to the potential discontinuations of subjects with antibody titres below the threshold of protection

Pharmacokinetic properties

Not applicable.

Preclinical safety data

Non-clinical data revealed no special hazard for humans based on animal studies.

Incompatibilities

In the absence of compatibilities studies, this vaccine must not be mixed with any other vaccine or medicinal products.

Shelf life

3 years.
After reconstitution: the product should be used once reconstituted.

Special precautions for storage

Store in a refrigerator (2–8°C).
Do not freeze.
Keep the vials in the outer carton in order to protect from light.
For storage conditions of the reconstituted product, see *section Shelf life*.

Special precautions for disposal and other handling

The freeze-dried vaccine should appear as a white to creamy white homogeneous cake which might be retracted from the sides of the vial.
The diluent should appear as a clear solution.
After reconstitution, IMOJEV® is a colourless to amber suspension.

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Contact with disinfectants is to be avoided since they may inactivate the vaccine virus.

Instructions for reconstitution and administration
Using aseptic technique, IMOJEV® vaccine is reconstituted by injecting all the 0.4% sodium chloride solution into the vial of freeze-dried vaccine, using the syringe and one of the needles provided in the carton. The vial is gently swirled. After complete dissolution, a 0.5 ml dose of the reconstituted suspension is withdrawn into this same syringe. For injection, the syringe is fitted with the second needle provided in the package.
The product should be used once reconstituted (*see section Shelf life*).

Disposal
After use, any remaining vaccine and container must be disposed of safely, preferably by heat inactivation or incineration, according to locally agreed procedures.

PACKAGING PRESENTATION :
Box, 1 vial + 1 vial of NaCl @ 0.5 mL + 1 syringe + 2 needles
Reg. No. DKI

Manufactured by:
Government Pharmaceutical Organization-Merieux Biological Products Co., Ltd.
241 Moo 7 Gateway City Industrial Estate,
Huasamrong, Plaengyao,
Chachoengsao 24190- Thailand

For Sanofi Pasteur Ltd. Thailand as a product owner

Imported by:
PT AVENTIS PHARMA
Jl. Jend. A. Yani Pulomas,
Jakarta - Indonesia

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

SANOFI PASTEUR

HARUS DENGAN RESEP DOKTER

RANCANGAN INFORMASI PRODUK UNTUK PASIEN

IMOJEV® dan IMOJEV®MD
Serbuk Injeksi + Pelarut
Vaksin Japanese encephalitis (Live attenuated)

* 0.4 % Sterile Sodium chloride solution (IMOJEV®)
* 0.9% Sterile Sodium chloride solution (IMOJEV®MD)

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1. APA YANG TERKANDUNG DALAM IMOJEV®DAN IMOJEV®MD ?

Tiap dosis (0.5mL) IMOJEV® dan IMOJEV®MD mengandung zat aktif Live Attenuated, virus recombinant Japanese encephalitis* 4.0-5.8 PFU Log**

* Diperbanyak Sel Vero
** Plaque Forming Unit

DALAM PROSES PEMBUATANNYA BERSINGGUNGAN DENGAN BAHAN BERSUMBER BABI

Bahan pembantu : Manitol, Laktosa, Asam Glutamat, Kalium Hidroksida, Histidin, Human Serum Albumin, Natrium klorida, Aqua Pro Injeksi.

Serbuk berwarna putih sampai putih krem homogen yang dapat ditarik dari sisi vial. Pelarut adalah larutan steril. Setelah dilarutkan, IMOJEV® dan IMOJEV®MD merupakan suspensi amber yang tidak berwarna.

2. UNTUK APA IMOJEV®DAN IMOJEV®MD DIGUNAKAN?

IMOJEV® dan IMOJEV®MD adalah vaksin yang digunakan untuk pencegahan Japanese encephalitis yang disebabkan oleh virus Japanese encephalitis yang diberikan pada pasien mulai dari usia 12 bulan ke atas.

3. BERAPA BANYAK DAN SEBERAPA SERING IMOJEV®DAN IMOJEV®MD INI DIGUNAKAN?

Pasien dengan usia 12 bulan ke atas : dosis IMOJEV® dan IMOJEV®MD 0.5 mL yang sudah dilarutkan dengan pelarut diberikan untuk imunisasi pertama

Pada anak-anak, jika perlindungan jangka panjang dibutuhkan, dosis booster IMOJEV® dan IMOJEV®MD diberikan setelah imunisasi pertama. Dosis booster lebih disukai diberikan 1 tahun setelah vaksinasi pertama dan dapat diberikan sampai 2 tahun setelah vaksinasi pertama. IMOJEV® dan IMOJEV®MD dapat diberikan sebagai vaksinasi booster pada anak-anak yang sebelumnya telah diberikan vaksin Inactivated Japanese encephalitis untuk vaksinasi pertama sesuai dengan waktu yang direkomendasikan untuk booster dari vaksin inactivated Japanese encephalitis.

Pada orang dewasa

Kekebalan dapat bertahan pada tingkat yang tinggi paling lambat 3 tahun setelah dosis penunjang diberikan.

Kebutuhan dan waktu pemberian untuk dosis booster belum dapat ditentukan.

Setelah serbuk vaksin dicampur dengan pelarut yang diberikan, vaksin digunakan melalui rute subkutan.

Pada pasien dengan umur 2 tahun ke atas, injeksi diberikan pada pada area deltoid pada bagian atas lengan. Pada pasien usia antara 12 dan 24 bulan, injeksi diberikan pada aspek anterolateral dari paha atau area deltoid. Vaksin tidak boleh diberikan secara intravaskular.

IMOJEV® dan IMOJEV®MD tidak boleh dicampur dengan vaksin lain atau produk obat. Kontak dengan disinfektan dihindari karena data membuat virus vaksin menjadi tidak aktif

4. PADA KEADAAN APA ANDA TIDAK DIPERBOLEHKAN MENGGUNAKAN IMOJEV® dan IMOJEV®MD?

IMOJEV® dan IMOJEV®MD tidak boleh diberikan untuk orang yang memiliki riwayat reaksi alergi yang parah terhadap vaksin atau riwayat reaksi alergi setelah pemberian vaksin sebelumnya atau vaksin yang berisi komponen atau zat yang sama. Vaksinasi harus ditunda jika ada deman atau penyakit akut lain.

Kekurangan kekebalan bawaan atau dapatan akan merusak kekebalan selular termasuk terapi imunosupresif seperti kemoterapi, dosis tinggi dari kortikosteroid sistemik yang diberikan secara umum selama 14 hari atau lebih (lihat nomor 5)

IMOJEV® dan IMOJEV®MD tidak boleh diberikan untuk penderita dengan ~~gejala~~ atau tanpa ~~infeksi HIV~~ yang disertai dengan bukti fungsi kekebalan yang terganggu

5. **APA YANG PERLU DIPERHATIKAN BILA MENGGUNAKAN IMOJEV® dan IMOJEV®MD?**
Jarang terjadi kasus anaphylactic pada pemberian vaksin ini. Tetapi jika terjadi, pengobatan dan pengawasan harus selalu disiapkan.
Untuk pasien yang mendapatkan pengobatan kortikosteroid sistemik dosis tinggi selama 14 hari atau lebih, disarankan untuk menunggu selambatnya satu bulan atau lebih sebelum diberikan vaksinasi sampai fungsi kekebalan.
Tidak dapat diberikan melalui injeksi intravascular

6. **OBAT DAN MAKANAN APA YANG HARUS DIHINDARI JIKA MENGGUNAKAN IMOJEV® dan IMOJEV®MD?**
IMOJEV® dan IMOJEV®MD dapat diberikan untuk orang dewasa bersama dengan vaksin yellow fever dengan menggunakan syringe yang terpisah dan diberikan pada anggota tubuh yang berbeda. Pada kasus terapi imunosupresif atau kortikosteroid, dapat dilihat pada bagian Nomor 4 dan 5
Pemberian vaksin pada orang yang sebelumnya menerima immunoglobulin: Untuk menghindari netralisasi dari virus yang dilemahkan pada vaksin, vaksinasi tidak boleh dilaksanakan dalam waktu 6 minggu dan lebih disukai tidak dalam waktu 3 bulan dari pemberian immunoglobulin atau produk darah yang berisi immunoglobulin seperti plasma darah

7. **APAKAH IMOJEV® dan IMOJEV®MD BOLEH DIGUNAKAN PADA WANITA HAMIL DAN MENYUSUI?**
Semua vaksin hidup yang dilemahkan tidak boleh diberikan kepada wanita hamil dan menyusui

8. **APAKAH BOLEH MENGENDARAI DAN MENJALANKAN MESIN SELAMA MENGGUNAKAN IMOJEV® dan IMOJEV®MD?**
Belum ada studi yang dilakukan untuk efek mengendarai dan menjalankan mesin selama menggunakan IMOJEV® dan IMOJEV®MD

9. **EFEK YANG TIDAK DIINGINKAN YANG MUNGKIN TERJADI**
Pada orang dewasa
Efek samping yang sangat umum terjadi (lebih dari 1 pada setiap 10 orang) : kelelahan, perasaan tidak sehat, nyeri pada area yang disuntik, sakit kepala, nyeri otot.
Efek samping yang umum terjadi (lebih dari 1 pada setiap 100 orang dan kurang dari 1 pada setiap 10 orang) : merasakan panas, menggigil. Kemerahan, gatal, bengkak dan memar pada area yang disuntik, pusing, nyeri sendi, diare, mual, muntah, nyeri perut. Nyeri pada tenggorokan, sesak, batuk, ingusan, hidung tersumbat, ruam.
Efek yang tidak umum (lebih dari 1 pada setiap 1000 orang dan kurang dari 1 pada setiap 100 orang): demam
Efek yang jarang terjadi lebih dari 1 pada setiap 10000 orang dan kurang dari 1 pada setiap 1000 orang) : Infeksi virus
Pada anak-anak:
Efek yang sangat umum (lebih dari 1 pada setiap 10 orang) : demam, perasaan tidak sehat, lekas marah, nyeri pada area yang disuntikkan, kemerahan pada area yang disuntikkan, sakit kepala, mengantuk, nyeri otot, muntah, kehilangan nafsu makan, menangis yang tidak normal
Efek yang umum terjadi (lebih dari 1 pada setiap 100 orang dan kurang dari 1 pada setiap 10 orang) : bengkak dan memar pada area yang disuntik

Efek yang tidak umum (lebih dari 1 pada setiap 1000 orang dan kurang dari 1 pada setiap 100 orang) : Reaksi di area injeksi (benjolan yang keras, gatal, memar, pembengkakan lokal dengan darah, perdarahan)
Efek yang jarang terjadi lebih dari 1 pada setiap 10000 orang dan kurang dari 1 pada setiap 1000 orang) : Ruam, gatal-gatal (urtikaria), ruam ditandai dengan spot
Jika terjadi efek samping yang serius atau efek samping yang tidak termasuk dalam list ini, segera beritahukan dokter anda atau apoteker

10. TANDA DAN GEJALA KELEBIHAN

Tidak ada kasus dan gejala kelebihan yang dilaporkan

11. **BAGAIMANA CARA MENYIMPAN OBAT INI?**

Simpan pada kulkas pada suhu 2-8°C. Jangan dibekukan. Simpan vial dalam dus supaya terhindar dari cahaya. Jangan menggunakan IMOJEV® dan IMOJEV®MD setelah tanggal masa kadaluarsa yang tercantum pada dus setelah kadaluarsa

12. PETUNJUK PENGGUNAAN

Vaksin IMOJEV® dilarutkan dengan menyuntikan larutan 0.4% NaCl kedalam vial yang berisi serbuk kering vaksin dengan menggunakan syringe dan satu jarum yang diberikan pada dus. Untuk IMOJEV ®MD, dilarutkan dengan menyuntikan larutan 0.9% NaCl
Vial diputar perlahan-lahan. Setelah dilarutkan secara sempurna, 0.5 mL dosis suspensi diambil dan ditarik ke dalam syringe yang sama. Untuk penyuntikkan, syringe dilengkapi dengan jarum kedua yang diberikan pada kemasan.
Produk harus segera digunakan setelah dilarutkan. Setelah digunakan, vaksin yang tertinggal dan kemasan harus segera dibuang dengan aman dan lebih baik diinaktifiasi dengan menggunakan panas atau pembakaran menurut prosedur lokal yang ditetapkan

13. NOMOR IJIN EDAR

IMOJEV, Dus, 1 vial @ 0.5 mL+1 vial pelarut+1 syringe+2 jarum : DKI....
IMOJEV ®MD, Dus, 10 vial@4 dosis @ 0.5 mL+10vial@4 dosis pelarut : DKI...

PRODUSEN

Government Pharmaceutical Organization-Merieux Biological Products Co., Ltd.
241 Moo 7 Gateway City Industrial Estate,
Huasamrong, Plaengyao,
Chachoengsao 24190 – THAILAND

Untuk Sanofi Pasteur Ltd. Thailand

PENDAFTAR

PT AVENTIS PHARMA
Jl. Jend. A. Yani Pulomas
Jakarta-Indonesia

HARUS DENGAN RESEP DOKTER

V3	18/07/2011 - SP
Code article : 961510	Sanofi Pasteur XA
09615106	Repères d'arêtes n° : 8
Etui - Dim. ext. : 85 x 22 x 135	
3 REF PANTONE : Reflex blue C (Texte) 2718 C (1/2 soleil + Dégradé) 298 C (Logo sanofi) Trace	

Note :
Generic Name will be enlarged in the final real packaging

IMOJEV®
Japanese encephalitis vaccine (live, attenuated)

HARUS DENGAN RESEP DOKTER

Powder and solvent for suspension for injection

1 dose of powder and 1 dose of solvent in separate vials with 1 syringe and 2 separate needles - pack size of 1 single dose of vaccine (0.5 mL)

Subcutaneous route

SANOFI PASTEUR

Statement of active substances
After reconstitution, one dose (0.5 mL) contains:
Live, attenuated, recombinant Japanese encephalitis virus:
4.0 – 5.8 log PFU*
(*Plaque Forming Unit)

List of excipients:
Powder: mannitol, lactose, glutamic acid, potassium hydroxide, histidine, human serum albumin.
Solvent: sodium chloride, water for injections.

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

Exp. :
Lot no. :
Ref. :

IMOJEV®
JAPANESE ENCEPHALITIS VACCINE (LIVE, ATTENUATED)

Sanofi Pasteur Ltd.
87/2 CRC Tower 23rd Floor, All Seasons Place building, Wireless Road, Lumphini, Pathumwan, Bangkok, Thailand

Reg. No.: DKI

Manufactured by:
Government Pharmaceutical Organization - Merieux Biological Products Co., Ltd.
241 Moo 7, Gateway City Industrial Estate, Hutsamrong, Plaengyao, Chachoengsao 24190, Thailand

ACC

Imported by:
PT Aventis Pharma
Jl. Jend A Yani Pulomas
Jakarta Indonesia

Store in a refrigerator (2°C to 8°C). Do not freeze.
Keep the vials in the outer carton in order to protect from light.
Keep out of reach and sight of children.

Directions for use: Read the package leaflet before use.
The vaccine should be used once reconstituted.
For single use only in one patient.
No adjuvant or antimicrobial preservative is added.

418 961490

Lot no.:
Mfg.:
HET : Rp.
Exp.:

HARUS DENGAN RESEP DOKTER

Reg. No.: DKI

Manufactured by:
Goverment Pharmaceutical Organization - Merieux Biological Products Co., Ltd. - Thailand
Imported by:
PT Aventis Pharma
Jakarta, Indonesia

IMOJEV®

JAPANESE ENCEPHALITIS VACCINE (LIVE, ATTENUATED)
(Live, attenuated, recombinant Japanese encephalitis virus 4.0-5.8 log PFU/0.5 mL)
POWDER FOR RECONSTITUTION FOR SUBCUTANEOUS INJECTION (1 DOSE)
Sanofi Pasteur

ACC

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

V3	18/07/2011 - SP
Code article : **961490**	Sanofi Pasteur XA
Etiquette : ☐ seringue ■ flacon ☐ tube	
Dimension : 22 x 44 mm	
1 REF. PANTONE : **Noir**	

418 961490

Lot no.:

IMOJEV®
JAPANESE ENCEPHALITIS VACCINE (LIVE, ATTENUATED)
(Live, attenuated, recombinant Japanese encephalitis virus 4.0-5.8 log PFU/0.5 mL)
POWDER FOR RECONSTITUTION FOR SUBCUTANEOUS INJECTION (1 DOSE)
Sanofi Pasteur

Lot no.:
Mfg.:
HET : Rp.
Exp.:

072 961500

Harus Dengan Resep Dokter

Sanofi Pasteur

Reg. No.: DKI
Imported by:
PT Aventis Pharma
Jakarta, Indonesia

SOLVENT 0.5 mL

0.4% STERILE SODIUM CHLORIDE SOLUTION FOR RECONSTITUTION OF IMOJEV® VACCINE (1 DOSE)

ACC

Manufactured by:
Government Pharmaceutical Organization - Merieux Biological Products Co., Ltd. - Thailand

V3	18/07/2011 - SP
Code article : 961500	Sanofi Pasteur XA
Etiquette : ☐ seringue ■ flacon ☐ tube	
Dimension : 22 x 44 mm	
1 REF. PANTONE : Noir	

Exp.:

072 961500

SOLVENT 0.5 mL
0.4% STERILE SODIUM CHLORIDE SOLUTION
FOR RECONSTITUTION OF IMOJEV® VACCINE (1 DOSE)
Sanofi Pasteur