INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

1. NAME OF THE MEDICINAL PRODUCT

Influenza vaccine (split virion, inactivated)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The Influenza vaccine (split virion, inactivated) in each 0.5 mL dose contains influenza virus antigens (cultured in chicken egg embryos, inactivated with beta-Propiolactone) equivalent to the following types and subtypes:

IVR-238 A/Victoria/4897/2022 (H1N1)pdm09 - like strain (H1N1)	15 μg HA
IVR-237 A/Thailand/8/2022 (H3N2) - like strain (H3N2)	15 μg HA
BVR-26 B/Austria/1359417/2021 (B/линия Victoria) - like strain (B)	15 μg HA
Preservative:	
Thiomersal	50 μg
Excipients:	
Phosphate-saline buffer solution (sodium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate, water for injection)	up to 0,5 mL

This vaccine complies with the WHO recommendation (for the Southern Hemisphere) for the 2024 season.

3. PHARMACEUTICAL FORM

Solution for intramuscular injection in multidose vial.

The vaccine is a colorless, slightly opalescent liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The Influenza vaccine (split virion, inactivated) is indicated for the prophylaxis of influenza caused by the seasonal viruses included in the vaccine.

The vaccine is indicated in adults and children aged 9 years and older (immunization is carried out using one dose of vaccine), people with chronic diseases and people aged 60 years and older.

Vaccination is carried out annually during the spring-summer period. Vaccination may also be carried out during the period when the influenza morbidity with epidemic character increases.

4.2 Posology and method of administration

The vaccine is administered in a single dose of 0.5 mL intramuscularly (into the deltoid muscle).

4.3 Contraindications

The vaccination should not be performed in case of the following condition:

- History of allergic reactions to chicken protein and any other vaccine component, see Section Qualitative and quantitative composition. Signs of an allergic reaction may include itchy skin (pruritus), breathing difficulty, and edema face or tongue.

4.4 Special warnings and precautions for use

Vaccination should be performed with caution in the following conditions:

- Acute febrile states or aggravation of chronic disease.

- In the case of not severe acute respiratory viral infections (ARVI) and acute intestinal diseases, vaccination shall be carried out after recovery (remission) of the disease.

The medical personnel conducting the vaccination should draw the patient's and the parent's or legal representatives' attention to the fact that if any of the adverse reactions indicated in the instructions are aggravated or any other side effects not specified in the instructions occur the doctor must be informed.

Consultation and vaccination centers, where the vaccination is carried out, must have all the necessary equipment and medicines required for the treatment of any adverse reaction that may develop after vaccination. It is recommended that vaccinees should be monitored for 30 minutes after vaccination.

See section 6.5 for more detailed information on disposal of a used medicinal product and other handling of the product.

4.5 Interaction with other medicinal products and other forms of interaction

The vaccine can be used simultaneously (on the same day) with other inactivated and live vaccines of the National Vaccination Schedule (except for rabies vaccines). In this case, the vaccines should be administered at different parts of the body (different limbs) using different syringes and needles.

The vaccine should not be mixed with any pharmaceutical products, including vaccines, in the same syringe.

The efficiency of vaccination can be adversely affected by an immunosuppressive therapy taken by the patient.

After influenza vaccination, an enzyme linked immunosorbent assay (ELISA) for HIV-1, hepatitis C virus and especially human T-cell lymphotropic virus type 1 (HTLV-1) can give false-positive results. These transient false-positive results can be caused by the production of cross-reacting IgM antibodies in response to the vaccine.

Therefore, in order to confirm the diagnosis of HIV-1, hepatitis C virus or human T-cell lymphotropic virus (HTLV-1), it is necessary to obtain a positive result of a confirming virus-specific test (e.g., the Western blot method or immunoblot).

4.6 Pregnancy and lactation

Pregnancy

WHO indicates that inactivated influenza vaccines may be given at all stages of pregnancy. The globally available safety data sets are broader for the second and third trimesters of pregnancy than for the first trimester. However, data on the use of inactivated influenza vaccines worldwide do not indicate any harmful effect on the fetus or the pregnant mother that can be attributed to the vaccine.

Given the existing evidences on the benefits of influenza vaccination in both the pregnant woman and the fetus, the vaccine may be used during pregnancy only under the advice of a health professional, taking into account the benefits and risks to the mother and fetus.

Breastfeeding

Influenza vaccine (split virion, inactivated) may be used during breastfeeding.

4.7 Effect on ability to drive and use machines

There is no indication of any untoward effect of vaccination regarding the ability to drive or use machines.

4.8 Adverse reactions

The frequency of side reactions reported in clinical trials is presented in accordance with the WHO classification of ADRs.

The frequency was determined according to the following criteria: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10000 and < 1/1000), very rare (<1/10000), unknown (frequency cannot be determined from available data).

Adults

The safety profile is based on data obtained:

- during clinical studies in 220 adults aged 18 to 60 years inclusive;
- during post-marketing use in the general population (*), more than 6,000,000 doses of the vaccine have been used since the start of sales;

Table 1. Adverse reactions observed in individuals aged 18 to 60 years.

Adverse reactions according to the classes of organ systems according to medical dictionary for MedDRA regulatory activities*	**Incidence**
Immune system disorders:	
Allergic reaction	Unknown*
Urticaria	
Psychiatric disorders:	
Low mood	Unknown*
Nervous system disorders:	
Headache**	Common
Dizzy spells**	
Taste metallic	Unknown*
Eye disorders:	
Itching eyes	Unknown*
Cardiac disorders:	
Palpitation	Unknown*
Tachycardia	
Respiratory, thoracic and mediastinal disorders:	
Cough	Common
Rhinorrhea**	
Oropharyngeal pain	
Persistent cough	Unknown*
Distress respiratory	
Sneezing	
Gastrointestinal disorders:	
Diarrhoea	Common
Nausea**	
Abdominal pain	

Vomiting	Unknown*
Skin and subcutaneous tissue disorders:	
Rash	Unknown*
Pruritis	
Redness facial	
Subcutaneous nodule	
Sweating	
Musculoskeletal and connective tissue disorders:	
Myalgia	Common
Arthralgia	
Cramps	Unknown*
General disorders and administration site conditions:	
Injection site pain	Common
Injection site erythema**	
Injection site edema**	
Injection site pruritus**	
Fatigue**	
Malaise	
Fever	
Febricula	Unknown*
Hypothermia	
Injection site inflammation	
Injection site induration	
Injection site redness	
Local reaction	
General malaise	
Chills	

** cases have also been reported in post-marketing use in this population, frequency unknown

Pediatric population

The safety profile is based on data obtained:

− during clinical studies in 20 children aged 6 to 12 years and 20 children/adolescents aged 12 to 17 years inclusive.

Table 2. Adverse reactions reported during clinical studies in the age group 6 to 17 years inclusive.

Adverse reactions according to the classes of organ systems according to medical dictionary for MedDRA regulatory activities*	**Incidence**
General disorders and administration site conditions:	

Injection site edema*	Common

* in children/adolescents aged 6 to 12 years

Elderly patients

The safety profile is based on data obtained:

- during clinical studies in 20 volunteers over 60 years of age;
- during post-marketing use in this population (*).

Table 3. Adverse reactions reported in individuals over 60 years of age.

Adverse reactions according to the classes of organ systems according to medical dictionary for MedDRA regulatory activities*	**Incidence**
Nervous system disorders:	
Headache**	Very common
Musculoskeletal and connective tissue disorders:	
Myalgia	Common
General disorders and administration site conditions:	
Injection site pain	Very common
Injection site pruritus	Common
Fever	Unknown *
Fatigue	Unknown *

** cases have also been reported in post-marketing use in this population, frequency unknown

Pregnant women

The safety profile is based on data obtained:

− during active pharmacovigilance in more than 63,000 pregnant women as part of a vaccination campaign in the Republic of Cuba.

Table 4. Adverse reactions reported in pregnant women

Adverse reactions according to the classes of organ systems according to medical dictionary for MedDRA regulatory activities*	**Incidence**
Immune system disorders:	
Vasculitis	Very rare
Nervous system disorders:	
Dizzy spells	Rare
Headache	Very rare
Loss of consciousness	
Hypotonic-hyporesponsive episode	
Facial paraesthesia	
Cardiac disorders:	
Tachycardia	Very rare
Respiratory, thoracic and mediastinal disorders:	
Cough	Very rare

Dyspnea	
Sputum	
Gastrointestinal disorders:	
Diarrhea	Very rare
Nausea	
Vomiting	
Skin and subcutaneous tissue disorders:	
Pruritis	Very rare
Rash	
Sweating	
Renal and urinary disorders:	
Dysuria	Very rare
General disorders and disorders at the injection site:	
Injection site erythema	Very rare
Pain at the injection site	
Injection site edema	
Fever	
General malaise	

The above adverse reactions develop on the day of vaccination, usually resolve on their own within 1-3 days and do not require any treatment. However, the development of other adverse reactions characteristic of influenza vaccines cannot be ruled out.

4.9 Overdose

Data on overdose with the vaccine is lacking.

5. PHARMACOTHERAPEUTIC GROUP

Viral vaccines, ATC code: J07BB02

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

There is no data of compatibility studies.

6.2 Shelf life

Unopened vial

One year (12 months) from the date of manufacture.

Opened vial

Opened multi-dose vials can be kept and used in subsequent immunization sessions for up to 28 days after first opening, provided that the following conditions are met: 1) the vaccine vial has been stored and will continue to be stored at 2-8 °C, 2) the expiry date of the vaccine has not passed. Do not use an expired product.

6.3 Special precautions for storage

The Influenza vaccine (split virion, inactivated) should be kept refrigerated at 2°C to 8°C. Do not freeze. Keep out of the reach of children. Keep the vial in the outer packaging to protect it from light.

6.4 Nature and contents of the package

10 multi-dose vials of 5 mL (10 doses of 0.5 mL each) of Influenza vaccine (split virion, inactivated), with a package leaflet.

6.5 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Before use, the vaccine should be removed from the refrigerator and left until it reaches room temperature, the vial should be shaken and the outer surface of the vial cap should be treated with a disinfectant solution before each dose is removed.

The extraction of each dose is done with a sterile disposable syringe and needle. A new syringe and needle must be used for each extraction. In the intervals between dose extractions and before at least 5 minutes after the last extraction, the vial should be placed in a refrigerator (not freezer) for storage at 2°C to 8°C. The vaccine from open multi-dose vials, after taking the first dose, must be used for subsequent immunization sessions within 28 days, provided that all use and storage requirements are met.

It is forbidden to use the vaccine contained in vials with evidence of violation of their physical integrity (of the container closure system) or in case of changes in physical properties (color, transparency, appearance of particles, precipitates), expiration of the vaccine and the effects of the cold chain or storage conditions violation.

The vaccine should always be visually inspected prior to administration.

The vaccine is only intended to be administered intramuscularly.

Pharmaceutical products should not be disposed of into sewers or together with household waste. Place vials from used medicinal products into containers for biological waste located in vaccination facilities for subsequent disinfection and processing by chemical or physical methods. If you have any doubts about the method of disposal of medicine waste and containers, please, contact a specialist. This will help protect the environment.

7. TRANSPORT CONDITIONS

At a temperature between 2°C and 8°C. **Do not freeze.**

8. MANUFACTURER

MARKETING AUTHORIZATION HOLDER AND MANUFACTURER

SPbSRIVS

The Federal State Unitary Enterprise “The Saint Petersburg Scientific Research Institute of Vaccines and Serums and the Enterprise for the Production of Bacterial Preparations” of Federal Medical and Biologic Agency
(FSUE SPBSRIVS FMBA)
Address: Russia, 198320, Saint-Petersburg, Krasnoe Selo, ul. Svobody, 52
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FILLING AND PACKAGING

Instituto Latinoamericano de Biotecnología MECHNIKOV, S.A.
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Tel: (505) 2299-2277, www.mechnikov.com

Complaints about Influenza vaccine (split virion, inactivated) quality defects as well as information about high reactogenicity or the development of medical complications associated with the use of the vaccine, should be submitted to FSUE SPbSRIVS FMBA of Russia and Instituto Latinoamericano de Biotecnología MECHNIKOV, S.A. with the indication of vaccine identification data specified on web-pages: www.spbniivs.ru and www.mechnikov.com

Registration Number in Cuba: B-16-015-J07
Registration Number in Nicaragua: 06000260419

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