VaxiPat® Adult

VaxiPat® Pediatric

Hepatitis A Vaccine (Human Diploid Cell), Inactivated

Suspension for injection Made in China - Prescription Only Medicine

QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1.0 ml dose for Adult use contains: Inactivated Hepatitis A virus antigen …..…….. 500 U
Each 0.5 ml dose for Pediatric use contains: Inactivated Hepatitis A virus antigen …..…….. 250 U
Excipients: aluminum hydroxide, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium chloride and water for injection.

THERAPEUTIC ACTION
Hepatitis A Vaccine.
Pharmacotherapeutic group: Viral Vaccine. ATC code: J07BC02

INDICATIONS
Vaxipat® is indicated for active immunization against infections caused by the hepatitis A virus.

CLINICAL PHARMACOLOGY
Pharmacodynamic Properties
Vaxipat® confers immunity against the hepatitis A virus by inducing higher antibody titres greater than those achieved after passive immunization with immunoglobulin. Antibodies initially appear after the first injection and after 14 days of vaccination more than 93% of immunocompetent subjects are seroprotected (titre above 20mIU/ml). At 28 days after the first dose, almost 100% of subjects have an antibody titre above 20mIU/ml.
The efficacy of Vaxipat® was evaluated in different communities. These studies indicated that the administration of a single dose contributes to termination of the outbreaks.
In one study, the peak of HAV outbreak began to decrease in 2 weeks after the first injection. In another study, the protective efficacy was 100% in students who received vaccination.
In order to ensure long-term protection, a booster dose should be given between 6 and 12 months after the first dose. In clinical studies, almost all vaccinated subjects are seropositive one month after the booster dose.
The long-term persistence of protective antibody levels to hepatitis A virus after a second dose (booster) of Vaxipat® has not been fully evaluated. Nevertheless, serological data show continuing protection against hepatitis A for up to 5 years in subjects who received full immunization.
Pharmacokinetic Properties
Not applicable to vaccines for prophylaxis.
Preclinical Safety Data
No toxicity was observed in long-term studies performed for Vaxipat® in mice and rats.

DOSAGE/POSOLOGY – METHOD OF ADMINISTRATION
Recommended dosage and regimen:

Age	Dose	Number of doses	Route of administration
Between 1 and 15 years	0.5 ml	2 (6 months interval)	Intramuscular
≥ 16 years	1.0 ml	2 (6 months interval)	Intramuscular

It is recommended to administrate a second dose (booster) of Hepatitis A Vaccine (Human Diploid Cell) to provide a long-term protection. The second dose is preferably given 6 months after the first dose.
Vaxipat® should be administered by intramuscular injection in the deltoid region.
In Argentina, the National Vaccination Calendar contemplates the administration of a single dose at 12 months of age.

CONTRAINDICATIONS
Subjects with known allergic reaction to any component of the vaccine, including excipients, formaldehyde and gentamycin sulphate.
Subjects with acute diseases, severe chronic diseases, experiencing exacerbations of chronic diseases or fever.

WARNINGS
Vaccines should be administered carefully in subjects with a history of seizures or epilepsy.
Immunization with this vaccine should differ in at least one month from the administration of immunoglobulin or other immunosuppressive treatment to avoid influencing the immune effect.
Appropriate medical treatments, such as Adrenaline, should be ready for immediate use in case of anaphylactic reactions occur following vaccination. Vaccinated subjects should be observed for at least 30 minutes on site following administration.
It is possible that subjects may be in the incubation period of hepatitis A infection at the time of immunization. It is not known whether Vaxipat® will prevent hepatitis A in such cases.

PRECAUTIONS
Drug interactions: Preliminary results suggest that simultaneous administration with a wide variety of other vaccines is unlikely to interfere with the immune response of Vaxipat®. Adverse reactions have been reported after simultaneous administration with other vaccines that were similar to those reported with a single vaccination. If Vaxipat® is required to be administered simultaneously with other vaccines, it should be done with different syringes and at different injection sites.
Interchangeability: Interchangeability studies with immunization between inactivated vaccines demonstrate that they appear to be well tolerated and indicate that interference in the immune response is difficult.
Pregnancy: Safety during pregnancy has not been well established, but there is no documented evidence of risk. Since the vaccine is prepared with inactivated virus, the risk to fetal development is likely to be insignificant. Vaxipat® should be administered to pregnant women only if clearly necessary and after an evaluation of the risks and benefits.
Lactation: It is not known whether Vaxipat® is excreted in human milk. As many drugs are excreted in human milk, the administration of Vaxipat® should be carried out with caution in breastfeeding women.
Effects on ability to drive and use machines: There is no clinical or scientific data for effects on ability to drive and use machines. It is not known whether Vaxipat® can affect the ability to drive and use machines.

ADVERSE REACTIONS
The safety profile shown below is based on data from clinical studies in addition to reactions observed through marketing surveillance.
Since it is not possible to calculate post-marketing reactions, the frequency data is noted as "unknown".
The most frequently reported reaction is fever, followed by pain at the injection site.
Frequencies per dose are defined as follows:
Very common: ≥ 10% / Common: ≥ 1% and < 10% / Uncommon: ≥ 0.1% and < 1% / Rare: ≥ 0.01% and < 0.1% / Very rare: < 0.01% / Unknown: Cannot be estimated with the available data.
Within each frequency group, adverse reactions are shown in decreasing order of severity.

System or Organs	Frequency	Adverse reaction
Injection site disorders	Common	Pain at the site injection (uncommon for the pediatric formulation of Vaxipat®).
	Uncommon	Reaction at the site injection, such as redness and swelling.
	Unknown	Induration at the site injection
General disorders of the body	Common	Fever
	Uncommon	Fatigue
Immune System Disorders	Rare	Anaphylaxis
Psychiatric Disorders	Unknown	Agitation*
Nervous System Disorders	Uncommon	Headache, Dizziness
	Unknown	Seizures*
Gastrointestinal Disorders	Uncommon	Vomiting
	Rare	Nausea, Diarrhea, Abdominal pain
Respiratory System Disorders	Uncommon	Coughing
	Unknown	Upper respiratory tract infection*
Skin Disorders	Rare	Rash
	Unknown	Urticaria*, Acute urticaria*, Erythema induratum*, Angioedema*
Vascular Disorders (extracardiac)	Unknown	Purpura allergic
General Disorders	Rare	Sore throat

These adverse reactions were identified through marketing surveillance, but were not observed in randomized controlled clinical studies. All data in the table except those marked with "" were calculated based on studies sponsored by the company.

Report of Suspected Adverse Reactions: It is very important to report suspected adverse reactions after the authorization of medicinal products. This allows to continue monitoring the risk/benefit balance of a medicinal product. Healthcare professionals must report any suspected adverse reactions to the health authority, ANMAT.

Information for Healthcare professionals
VaxiPat® is included within a Risk Management Plan (set of Pharmacovigilance activities to prevent or minimize risks related to medicinal products).

OVERDOSE
Few cases of overdose have been reported with Vaxipat® during commercialization. The adverse reactions reported after an overdose were similar to those reported with a normal vaccination.
In case of overdose, attend to the local Hospital or contact Toxicology Centers, available 24 hours a day:
- Hospital de Pediatría Ricardo Gutiérrez: (011) 4962 – 6666 / 2247
- Hospital Pedro Elizalde (ex Casa Cuna): (011) 4300 – 2115
- Hospital Nacional Profesor Dr. Alejandro Posadas: (011) 4654 – 6648 / 4658 -7777

STORAGE CONDITIONS
Store at 2°C to 8°C, protect from light. DO NOT FREEZE.

PRESENTATIONS
For Children
Package containing 1, 10, 20, or 50 pre-filled single-dose syringes of 0.5 ml each.
Package containing 1, 10, 20, or 50 single-dose vials of 0.5 ml each.
For Adults
Package containing 1, 10, 20, or 50 pre-filled single-dose syringes of 1.0 ml each.
Package containing 1, 10, 20, or 50 single-dose vials of 1.0 ml each.

This medicine must be used only under medical prescription and supervision and cannot be repeated without a new medical prescription.

KEEP OUT OF REACH OF CHILDREN

Medicinal Product authorized by the Ministry of Health - Certificate No. 59.162.

Manufactured and labeled by: Sinovac Biotech Co., Ltd.
No. 15, Zhi Tong Road, Changping Science Park, Changping District, Beijing, P.R. China
No. 39 Shangdi Xi Rd., Haidian District, Beijing, P.R. China
Packaged by: Sinergium Biotech S.A.
Route 9 km 38.7 Garín, Province of Buenos Aires, Argentina.
Technical Director: Sebastián Enrique Comellas - Pharmacist.

Date of last revision: April 2025