

## To persons desiring a rabies vaccination (Rabipur for intramuscular injection):

At the time of rabies vaccination (Rabipur for intramuscular injection), it is necessary to fully grasp the health status of the person to be vaccinated. Please read the explanation below, then fill in the "Inquiry form for rabies vaccination (Rabipur for intramuscular injection)" and undergo a doctor's examination. For minors, a guardian familiar with the health status of the child is requested to fill in the form.

### About rabies:

Rabies infection occurs when bitten by an animal infected with the rabies virus (dog, cat, fox, bat, etc.) or when a wound is licked by such animal. The incubation period is usually 1-3 months. After onset, there are no effective curative methods. Starting with headache and fever, this is followed by difficulty in swallowing, and convulsions, etc. that result in death due to respiratory/circulatory failure with an almost 100% mortality rate. Except for some countries and regions, rabies exists all over the world, but is most prevalent in Asian and African countries. In Japan, there have been no cases of infection since 1957, but in other countries, about 50 to 60 thousand people die of rabies every year.

The basic countermeasure against rabies is "pre-exposure vaccination". If traveling to a region where the risk of rabies infection is high, "pre-exposure vaccination", i.e., prior vaccination, is effective. Vaccination against rabies before travel is recommended for those persons making an extended stay exceeding one month, for those persons who will come into frequent contact with animals regardless of the length of stay and for those persons unable to easily visit a medical institution given that they are traveling to a remote or unexplored region. When rabies infection from an animal bite is suspected, "post-exposure vaccination", i.e., being vaccinated immediately after the event, is an effective measure. When pre-exposure vaccination is not performed, dependent upon the extent of the contact it may be necessary to administer immunoglobulin.

Ministry of Health, Labour and Welfare: Q&A related to rabies  
"https://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou10/07.html, checked on October 22, 2021"  
Quarantine Station, Ministry of Health, Labour and Welfare (FORTH): Infection information, rabies  
"https://www.forth.go.jp/useful/infectious/name/name47.html, checked on October 22, 2021"

### Effects and adverse reactions of this vaccine

"Rabipur for intramuscular injection" is a vaccine suitable for use both as a preventive vaccination performed before traveling to a rabies endemic area (pre-exposure vaccination) and also for onset prevention after an animal bite in a rabies existing country (post-exposure vaccination).

The major adverse reactions are injection site pain/redness/swelling with the possibility of systemic symptoms such as headaches, malaise and fever. In addition, as serious adverse reactions, shock and anaphylaxis (an allergic reaction accompanied by decreased blood pressure, difficulty in breathing or systemic urticaria appearing usually within 30 minutes after inoculation), encephalitis and Guillain-Barré syndrome (bilateral limb numbness, gait disorder, etc.) may present. Since this product contains gelatin, if you are hypersensitive to a medicine or food containing gelatin, ensure that you report this to the doctor.

### Persons who must not undergo preventive vaccination:

- (1) Persons with fever (37.5°C or higher).
- (2) Persons clearly suffering from an acute disease.
- (3) Persons who have had an anaphylactic reaction to any component of this vaccine (allergic reaction accompanied by decreased blood pressure, difficulty in breathing or systemic urticaria appearing usually within 30 minutes after inoculation).
- (4) In addition, persons who are judged to be unsuitable for preventive vaccination by the doctor.

Note that this vaccine may be used as a post-exposure vaccination after taking the therapeutic benefit into consideration.

### Persons who must consult doctor prior to preventive vaccination:

- (1) Persons with a history of hypersensitivity to a medicine or food containing gelatin.
- (2) Persons with an underlying disease related to the cardiovascular system, kidneys, liver or blood or a developmental disorder.
- (3) Persons who developed a fever or a symptom suggestive of allergy, such as systemic rash, within 2 days after a previous preventive vaccination.
- (4) Persons with a history of convulsions (seizures).
- (5) Persons who have been diagnosed with immunodeficiency in the past or have a relative with congenital immunodeficiency.
- (6) Persons who have exhibited symptoms suggestive of an allergic reaction to a component of this vaccine, to chicken eggs/meat, or an antibiotic agent (such as tetracycline, neomycin and amphotericin B), etc.
- (7) Persons with a low platelet count or bleeding tendency.
- (8) Persons who are or may be pregnant.
- (9) Persons who have had any preventive vaccination in the last month.

### Post-vaccination Cautions

- (1) As fainting may occur after vaccination, please relax in a chair with a backrest at the vaccination facility for about 30 minutes after inoculation. Return home only after no change in physical condition has been verified.
- (2) Avoid strenuous exercise on the day of inoculation and keep the injection site clean. You can take a bath on the day of inoculation.
- (3) If you feel any abnormal reaction at the injection site or change in physical condition after inoculation or if any abnormal symptom such as a high fever occur or if you suffer from convulsions, immediately present at a clinic or hospital for an examination.
- (4) In the event that any adverse health effects arise as a result of inoculation with this vaccine, treatment expenses, etc. may be paid based on the "Adverse Drug Reaction Relief System". For further details, please refer to the Pharmaceuticals and Medical Devices Agency website.

Planned Inoculation date	MM DD ( ) Around _____:_____	Name of medical institution	
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\*If you desire to be vaccinated, fill in the boxes below:

## Screening Questionnaire for Rabies Vaccination (Rabipur for intramuscular injection)

		Body temperature before interview		°C	
Number of Doses	First/Second/Third/ th times, Last Vaccination Date:			/ / (dd/mm/yy)	
Address				TEL No.	
Patient's Name	M	Birth Date	/ / (dd/mm/yy)		
	F	Age (	/	/	years months)

Questionnaire for Vaccination	Answer		Doctor's Comment
Have you read and understood the explanation about the vaccination that will be administered today?	No	Yes	
Do you currently have any sort of illness? Are you feeling sick today?	Yes If so, please describe in detail. ( )	No	
Are you receiving any treatment (e.g., medicines) for the illness?	Yes Name/type of the medicine ( )	No	
Have you been ill in the past month?	Yes Disease name ( )	No	
Do you have a health problem with heart disease, kidney disease, liver disease, hematologic disease, immune deficiency, or others for which you have consulted a doctor? Where relevant, did the doctor who manages the above disease agree with today's vaccination?	Yes Disease name ( ) No	No Yes	
(If the vaccination is for a child) Were there any problems with the child's health at delivery, after birth, or at infant health check?	Yes Describe in specific ( )	No	
Have you ever had a seizure (spasm or fit) in the past? Did you have a fever at that time?	Yes At ( ) years old Yes	No	
Have you ever had a rash or urticaria (hives or 'nettle rash') as a reaction to medications or food, or become ill after eating certain foods or receiving certain medications?	Yes Food or medication name ( )	No	
Have you ever experienced a decreased blood pressure, shock or anaphylaxis (allergic reaction that usually develops within 30 min after vaccination associating with breathing difficulty and/or generalized hives) to medicines or food containing gelatin?	Yes	No	
Have any of your family members or relatives had a serious reaction to a vaccine in the past?	Yes Vaccine name ( )	No	
Do you have a family member or relative with a congenital immunodeficiency?	Yes	No	
Have any of your family or anyone around you contracted measles, rubella, chickenpox, or mumps in the past month?	Yes Disease name ( )	No	
Have you been vaccinated in the past month?	Yes Vaccine name ( ) Date administered: / (dd/mm)	No	
Have you had a serious reaction to a vaccine in the past?	Yes Vaccine name ( )	No	
(Women only) Are you pregnant or possibly pregnant?	Yes	No	
Do you have any questions about today's vaccination?	Yes Describe in specific ( )	No	

<b>Doctor's Comment</b> Based on the above answers and the results of interview, I have decided that the patient (can / should not) receive a vaccination today. I have explained to the patient (or the guardians) the information concerning the benefits and side effects of vaccination as well as the Relief System for Sufferers from Adverse Drug Reactions.	Signature or Name and Seal of Doctor: _____
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Having interviewed and explained by the doctor, do you wish to receive a vaccination with the understanding of the benefits and side effects of vaccination and the Relief System for Sufferers from Adverse Drug Reactions?  Yes / No	Signature of the Patient or Proxy _____ If proxy signs, describe relationship _____
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Vaccine Name	Vaccination Site, Dosage, and Administration	Institution, Doctor Name, Date Administered
Rabipur Inactivated Rabies Virus Vaccine GlaxoSmithKline K.K. Lot No.:	Intramuscular injection, 1.0 ML (R / L)	Institution Doctor Name Date / / (dd/mm/yy) Administered At : am /pm

This screening questionnaire is used to ensure the safety of vaccination. The personal information described here will be used only for screening for vaccination.