MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

INSTRUCTIONS FOR USE OF THE MEDICINAL PRODUCT

Grippol® Quadrivalent

Quadrivalent inactivated subunit adjuvant influenza vaccine

Registration certificate:

Trade name: Grippol® Quadrivalent

Quadrivalent inactivated subunit adjuvant influenza vaccine

Group name: Influenza prevention vaccine [inactivated] + Azoximer bromide

Dosage form: solution for intramuscular and subcutaneous injection

Composition per 1 dose (0.5 ml):

Active ingredients:

Type A (H_1N_1)* influenza virus antigen	
with concentration of hemagglutinin	- 5 μg
Type A (H_3N_2)* influenza virus antigen	
with concentration of hemagglutinin	- 5 μg
Type B influenza virus antigen (Yamagata line)*	
with concentration of hemagglutinin	- 5 μg
Type B influenza virus antigen (Victoria line)*	
with concentration of hemagglutinin	- 5 μg
Polyoxidonium®, freeze-dried substance** (Azoximer bromide)	- 500 μg
Excipients:	
PBS - phosphate-buffered saline	up to 0.5 ml

* - *strains of influenza virus antigen - in accordance with the guidelines of WHO for the current epidemic season for the Northern hemisphere;*

** - *equivalent to active ingredient Azoximer bromide, excipients - mannitol, povidone.*

Notes.

1. The composition of the phosphate-buffered saline: potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, sodium chloride, water for injections.
2. Triton X-100 may be present as an excipient in influenza virus antigens.

Appearance

Colorless or white off slightly opalescent fluid.

Product specification

The vaccine is protective antigens (hemagglutinin and neuraminidase) of epidemically actual strains of subtypes A (H1N1), A(H3N2) of type A and type B Yamagata line and Victoria line influenza viruses, isolated from virus-containing chick-embryo allantoic fluid in combination with immunoadjuvant Polyoxidonium® (INN: Azoximer bromide).

The strain composition of the vaccine is updated annually in accordance with the epidemic situation and WHO recommendations for the Northern Hemisphere.

Pharmacotherapeutic group: MIBP-vaccine.

ATC code: J07BB02.

Immunological properties

The vaccine induces formation of high level of specific immune response against influenza. The protective effect post vaccination generally develops after 8-12 days and preserves till 12 months.

Addition of immunoadjuvant Polyoxidonium® to the vaccine, which provides broad spectrum of immunopharmacological action, ensures increased immunogenicity and antigen stability, allows to increase immunological memory, significantly reduces vaccine dose of antigens, increases body resistance to other infections by adjusting its immune status.

Indications for use

Specific flu prevention in children aged 6 months, adolescents and adults up to 60 years.

The vaccine is specifically indicated for:

1. *Individuals at high risk for influenza-associated complications:*

– individuals, who frequently fall ill with ARD, suffering from chronic somatic diseases, including: diseases and congenital anomalies of central nervous system, cardiovascular and broncho-pulmonary system, bronchial asthma, chronic kidney diseases, diabetes mellitus, metabolic diseases, autoimmune diseases, allergic diseases (except for allergy to chicken proteins); chronic anemia, hereditary or acquired immunodeficiency, HIV-associated;

2. Individuals with high occupational risk of influenza infection or influenza contamination of other individuals:

- medical staff, citizens who are subject to call-up for military service, employees of educational institutions, social service sphere, transport, trade, police, individuals, engaged in poultry industry, members of the military etc.

Contraindications

– Allergic reactions to chicken protein and vaccine components.

– Allergic reactions to previously administered influenza vaccines.

- Strong reaction (temperature is above 40 °C, edema and hyperemia at injection site over 8 cm in diameter) or history of complications to previous administration of influenza vaccines.
- Acute infectious or non-infectious diseases, exacerbations of chronic diseases – vaccinations are carried out 2-4 weeks after recovery or during convalescence or remission.
- In non-severe ARVI, acute intestinal diseases the vaccination is performed after normalization of temperature.
– Children age under 6 months.

Safety precautions

Not for intravenous injection!

Anti-shock medicinal products should be envisaged in rooms, where vaccination is performed.

A vaccinated person should be under follow-up with healthcare provider for 30 min post immunization.

Use during pregnancy and lactation

The decision concerning immunization of pregnant women should be taken individually by a physician considering a risk of influenza infection and possible complications of influenza infection. The immunization is safest at the second and third trimester.

Breastfeeding is not a contraindication for immunization.

Dosage and Administration

The vaccination is performed annually in the autumn-winter period. The vaccination is possible at the beginning of epidemic raise of flu morbidity.

For children over 3 years of age, adolescents and adults, vaccine is injected intramuscularly or deep subcutaneously into the upper third of external surface of the upper arm (into the deltoid), younger children – intramuscularly into the thigh anterolateral surface.

For children aged 6 through 35 months – 0.25 ml twice with 3–4 weeks interval.

Children over 36 months of age and adults – vaccine may be given once at a dose of 0.5 ml.

For patients with immunodeficiency and those receiving immunosuppressive therapy – vaccine may be given twice in a dose of 0.5 ml with 3–4 weeks interval.

Before use, leave vaccine to reach ambient temperature and shake well.

Using a syringe, it is necessary to take off a protective cap from the needle and remove the air out of syringe, holding it in the vertical position with the needle upwards and slowly pressing to a plunger.

To immunize children for whom 0.25 ml (1/2 dose) of the vaccine is indicated, eject half of the syringe contents by pressing the plunger in to the mark on the syringe body or to the green mark on the label edge, and inject remaining dose of 0.25 ml.

Side effects

Vaccine is highly purified and well-tolerated.

The rate of adverse events, registered during conduction of clinical trials, is presented in accordance with the ADR WHO classification.

The rate of adverse events across the WHO classification: very frequent (>1/10), frequent (>1/100 and <1/10), infrequent (>1/1000 and <1/100), rare (>1/10000 and <1/1000), very rare (<1/10000).

Blood and lymphatic system disorders: rare – enlarged lymph nodes.

Nervous system disorders: frequent – headache.

Respiratory, thoracic and mediastinum-related disorders: frequent - runny nose, throat hyperemia, infrequent - sore throat.

Musculoskeletal and connective tissue disorders: infrequent - myalgia, arthralgia.

General disorders and administration site conditions:

- general disorders: frequent – malaise;
- administration site conditions: very frequent - pain, redness, formation of indurations (infiltration) and swelling at administration site, frequent - itch at administration site.

Laboratory and instrumental data: infrequent - increased body temperature.

Most reactions are generally resolved spontaneously within 2-3 days.

Although there are no clinical findings, it is impossible to eliminate the possibility of the development of neurological disorders and allergic reactions (including immediate reactions, to chicken protein and other vaccinal components) characteristic for influenza vaccines.

Patient should be instructed to notify the physician of any apparent or not specified in this instruction adverse events.

Overdosage

No case of overdoses registered.

Interactions with other medicinal products

Grippol® Quadrivalent inactivated subunit adjuvant influenza vaccine may be administered concomitantly with inactivated and live vaccines according to National Immunization Schedule (excluding BCG and BCG-M) and inactivated vaccines from Immunization Schedule by epidemic indications (excluding antirabic vaccines). However, contraindications to each of the used vaccine should be taken into account; the medicinal products should be administered in different parts of the body using different syringes.

The vaccine should be administered on basis therapy, available in vaccinated disease. The immunization of patients, receiving immunosuppressive therapy (glucocorticosteroids, cytostatic preparations, radiotherapy) may be less effective.

Special warnings and precautions for use

On day of vaccination the individuals being vaccinated should be examined by a physician (physician assistant) with compulsory thermometry. The vaccination is not performed at temperature over 37.0 °C.

The medicinal product in syringes with disturbed integrity and labeling, with changed physical properties (color, clarity), with expired date, impaired requirements for storage is not suitable for use.

Effect on ability to drive and operate machinery

Grippol® Quadrivalent vaccine against influenza quadrivalent inactivated subunit adjuvant causes no effect of ability to drive and use machines.

Dosage form

Solution for intramuscular and subcutaneous injection.

0.5 ml (1 dose) in single-use syringes.

1, 5 or 10 syringes in a blister pack made of polyvinyl chloride film, coated with polymer-coated aluminum foil.

1 blister (containing 1 or 5 syringes or 10 syringes) or 2 blisters (containing 5 syringes) in a cardboard box together with the package leaflet.

Storage conditions

Keep in a dark place at the temperature 2 to 8°C. Do not freeze. Do not use product after freezing.

Keep out of the reach of children.

Transportation conditions

Keep in a dark place at the temperature 2 to 8°C. Do not freeze. May be transported at a temperature not exceeding 25°C for not more than 24 hours.

Shelf life

1 year Do not use after the expiry date.

Dispensing conditions

Package containing 1 syringe, available by prescription.

Packaging containing 5 or 10 syringes distributed to healthcare institutions.

Manufacturer / Legal entity that obtained the marketing authorization

NPO Petrovax Pharm, LLC

1, Sosnovaya str., Pokrov village, Podolsk city, Moscow Region,

142143 Russia

Tel./Fax: +7(495) 926-21-07,

email: info@petrovax.ru

The organization that accepts customer claims

NPO Petrovax Pharm, LLC

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142143 Russia

Tel.: +7(495) 730-75-45, 8 800 234-44-80,

email: adr@petrovax.ru

Send complaints about product quality related to physical properties, dispensing, packaging, and information about cases of increased reactogenicity or development of post-vaccination complications, with mandatory indication of the series number and manufacturing date, followed by the submission of medical records, to the manufacturer NPO Petrovax Pharm, LLC and to the Federal Service for Healthcare Surveillance (Roszdravnadzor).