

New Zealand Data Sheet

NAME OF THE MEDICINE

VAXIGRIP®

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION)

DESCRIPTION

VAXIGRIP is a sterile suspension of influenza virus for intramuscular or deep subcutaneous injection. It is a purified, inactivated, split virion vaccine.

VAXIGRIP contains the following strains of influenza virus:

- A/Michigan/45/2015 NYMC X-275 (A/Michigan/45/2015 [H1N1]pdm09-like),
- A/Hong Kong/4801/2014 NYMC X-263B (A/Hong Kong/4801/2014 [H3N2]-like) and
- B/Brisbane/60/2008 wild type (B/Brisbane/60/2008-like)

Each 0.5 mL pre-filled syringe contains 15 µg haemagglutinin of each of the 3 strains in a buffered saline solution. A buffered saline solution contains the following excipients – sodium chloride, potassium chloride, sodium phosphate – dibasic dihydrate, potassium phosphate – monobasic and water for injection.

The vaccine is prepared from virus grown in the allantoic cavity of embryonated eggs, concentrated, purified by zonal centrifugation in a sucrose gradient, split by octoxinol 9 (Triton X-100), inactivated by formaldehyde and then diluted in phosphate buffered saline solution to the required concentration. No adjuvant or preservative is added. The vaccine may contain traces of formaldehyde (≤ 30 µg), octoxinol 9 (≤ 200 µg) and neomycin (≤ 20 picogram). VAXIGRIP does not contain more than 0.05 µg ovalbumin per dose.

The type and amount of viral antigens contained in VAXIGRIP conform to the annual requirements of the Australian Influenza Vaccine Committee (AIVC) and the World Health Organization (WHO) recommendations for the season.

PHARMACOLOGY

Influenza vaccines have been shown to give antibody responses and to provide protection against clinical illness in a proportion of vaccinees. Because the influenza virus is capricious antigenically and because significant changes in its antigenic behaviour may occur from time to time, protection afforded by VAXIGRIP is limited to the strains from which the vaccine has been prepared or to closely related strains.

Seroprotection is generally obtained within 2 to 3 weeks.

INDICATIONS

VAXIGRIP is indicated for the prevention of influenza caused by Influenza Virus types A and B in adults and children aged 6 months and over.

The current New Zealand Immunisation Handbook recommends that influenza vaccine be administered to any person, 6 months of age or over, where it is desirable to reduce the likelihood of becoming ill with influenza.

For full details regarding these recommendations for influenza vaccination, refer to the current New Zealand Immunisation Handbook.

CONTRAINDICATIONS

VAXIGRIP should not be given to persons with a history of severe allergic reaction to egg proteins (eggs or egg products), to chicken proteins, to any other component of the vaccine including traces (formaldehyde, octoxinol 9 (Triton X-100) and neomycin) or after previous administration of the vaccine or a vaccine containing the same components.

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

PRECAUTIONS

As each dose may contain traces of formaldehyde and octoxinol 9 (Triton X-100) which are used during vaccine production, caution should be exercised when the vaccine is administered to persons with a hypersensitivity to any of these substances.

As each dose may contain undetectable traces of neomycin, which is used during vaccine production, caution should be exercised when the vaccine is administered to persons with hypersensitivity to this antibiotic (and other antibiotics of the same class).

As with any vaccine, vaccination with VAXIGRIP may not protect 100% of susceptible persons.

Patients with a history of Guillain-Barré Syndrome (GBS) with an onset related in time to influenza vaccination may be at increased risk of again developing GBS, but whether vaccination specifically might increase the risk for recurrence is unknown. Because patients with a history of GBS have an increased likelihood of again developing the syndrome, the chance of them coincidentally developing the syndrome following influenza vaccination may be higher than in individuals with no history of GBS. If GBS has occurred within 6 weeks following previous influenza vaccination, the decision to give VAXIGRIP should be based on careful consideration of the potential benefits and risks.

If the vaccine is used in persons deficient in producing antibodies, whether due to genetic defect, immunodeficiency disease, or immunosuppressive therapy, the expected immune response may not be obtained.

Do not administer by intravascular injection.

As with all injectable vaccines, the vaccine must be administered with caution to persons with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these persons.

As with all injectable vaccines, appropriate medical treatment and supervision should always be available in case of anaphylactic reactions. Adrenaline should always be ready for immediate use whenever any injection is given.

Effects on Fertility

VAXIGRIP has not been evaluated for the effects on fertility.

Use in Pregnancy (Category B1)

Animal reproductive studies have not been conducted with VAXIGRIP.

For VAXIGRIP, no clinical trial data on exposed pregnancy are available.

Data from worldwide use of inactivated influenza vaccines in pregnant women and experience of use of VAXIGRIP in countries where inactivated influenza vaccines are recommended in all stages of pregnancy do not indicate any adverse fetal and maternal outcomes attributable to the vaccine.

VAXIGRIP should be given to a pregnant woman following an assessment of the risks and benefits. Health authorities recommend vaccination of pregnant women.

Refer to the current New Zealand Immunisation Handbook for guidance on the use of influenza vaccines during pregnancy.

Use in Lactation

There are no data in breastfed newborns/infants of women vaccinated with VAXIGRIP during breastfeeding period. However, based on inactivated influenza vaccines experience, VAXIGRIP may be used during breastfeeding.

Paediatric Use

VAXIGRIP is not recommended in children below the age of 6 months.

Use in the Elderly

Annual influenza vaccination is recommended for persons 65 years of age and over.

Genotoxicity

VAXIGRIP has not been tested for genotoxic potential.

Carcinogenicity

VAXIGRIP has not been tested for carcinogenic potential.

Effects on Laboratory Tests

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique can be used to disprove these results. The transient false positive reactions could be due to IgM response by the vaccine.

INTERACTIONS WITH OTHER MEDICINES

Clinical data showing that VAXIGRIP may be administered concomitantly with other vaccines are available for the following vaccines: 23-valent pneumococcal polysaccharide vaccine in elderly, dTpa-IPV (diphtheria-tetanus-acellular pertussis-

inactivated poliovirus vaccine) in adults aged ≥ 60 years, and zoster vaccine in adults aged 50 and older.

VAXIGRIP can be given at the same time as other vaccines.

Separate injection sites and separate syringe should be used in case of concomitant administration.

Although an inhibition of hepatic clearance of phenytoin, theophylline and warfarin has been reported after influenza vaccination, subsequent studies have not shown any evidence of undesirable effects related to this phenomenon.

If the vaccine is used in persons deficient in producing antibodies due to immunosuppressive therapy, the expected immune response may not be obtained.

ADVERSE EFFECTS

Adverse event information is derived from uncontrolled clinical trials and worldwide post-marketing experience.

Data from clinical studies

Within each system organ class the adverse events are ranked under headings of frequency, most frequent reactions first, using the following convention:

Very common: $\geq 1/10$ ($\geq 10\%$)

Common: $\geq 1/100$, $<1/10$ ($\geq 1\%$ and $< 10\%$)

Uncommon: $\geq 1/1000$, $<1/100$ ($\geq 0.1\%$ and $< 1\%$)

Rare: $\geq 1/10\ 000$, $<1/1000$ ($\geq 0.01\%$ and $< 0.1\%$)

Very rare: $<1/10\ 000$ ($< 0.01\%$)

Not known (cannot be estimated from the available data)

For the purpose of the cumulative safety analysis, clinical data from 36 studies using the VAXIGRIP/VAXIGRIP Junior thiomersal-free formulation conducted since 2001 were considered.

A total number of 10,880 persons received an intramuscular injection of VAXIGRIP/VAXIGRIP Junior:

- 54 children from 6 to 35 months received one or two 0.25 mL doses of VAXIGRIP Junior depending on their immunisation history
- 460 children from 3 to 8 years received one or two 0.5 mL doses of VAXIGRIP depending on their immunisation history
- 72 children/adolescents from 9 to 17 years, 4775 adults from 18 to 60 years and 5519 elderly over 60 years of age received one 0.5 mL dose of VAXIGRIP

Solicited reactions usually occurred within the first 3 days following VAXIGRIP/VAXIGRIP Junior, resolved spontaneously within 1 to 3 days after onset. Most of the solicited adverse reactions were of mild to moderate intensity.

Adults and elderly

A total of 4775 adults from 18 to 60 years and 5519 elderly over 60 years of age received one 0.5 mL dose of VAXIGRIP in 31 clinical trials. Several studies included both adult and elderly.

The table below summarises frequencies (weighted average from studies on the basis of study size) of solicited adverse reactions that were recorded within 3 days following vaccination in 4469 adults and 4761 elderly.

Table 1: Solicited adverse reactions within 3 days after vaccination of 9230 persons who received VAXIGRIP

Adverse reactions	Adult 18-59 Years (N=4469)	Elderly ≥ 60 Years (N=4761)
General Disorders and Administration Site Conditions		
<i>Local reactions:</i>		
Injection site pain/tenderness	45.9% (Very common)	18.9% (Very common)
Injection site erythema/redness	16.5% (Very common)	19.1% (Very common)
Injection site induration	15.9% (Very common)	14.1% (Very common)
Injection site oedema/swelling	10.9% (Very common)	11.2% (Very common)
Injection site bruising/ecchymosis	3.3% (Common)	3.9% (Common)
Injection site pruritus*	9.6% (Common)	7.1% (Common)
<i>Systemic complaints:</i>		
Asthenia†	18.8% (Very common)	4.6% (Common)
Pyrexia (oral temperature > 38°C)	1.9% (Common)	2.2% (Common)
Rigors/Shivering	6.4% (Common)	3.1% (Common)
Malaise	11% (Very common)	6.8% (Common)
Nervous system disorders		
Headache	19.1% (Very common)	10.6% (Very common)
Musculoskeletal and connective tissue disorders		
Arthralgia†	6.3% (Common)	1.3% (Common)
Myalgia	19.8% (Very common)	9.7% (Common)
Skin and subcutaneous tissue disorders		
Sweating increased†	7.7% (Common)	1.3% (Common)

* In adults, adverse reactions reported in 11/21 studies (3643 adults). In elderly, adverse reactions reported in 9/19 studies (3732 elderly).

† In adults, adverse reactions reported in 6/21 studies (2013 adults). In elderly, adverse reactions reported in 5/19 studies (388 elderly).

The table below summarises frequencies (weighted average from studies on the basis of study size) of solicited adverse reactions that were recorded within 7 days following vaccination in 4380 adults and 5058 elderly.

Table 2: Solicited adverse reactions within 7 days after vaccination of 9438 persons who received VAXIGRIP

Adverse reactions	Adult 18-59 Years (N=4380)	Elderly ≥ 60 Years (N=5058)
General Disorders and Administration Site Conditions		

Adverse reactions	Adult 18-59 Years (N=4380)	Elderly ≥ 60 Years (N=5058)
Local reactions:		
Injection site pain/tenderness	45.4% (Very common)	18.2% (Very common)
Injection site erythema/redness	17.3% (Very common)	17.6% (Very common)
Injection site induration	17.1% (Very common)	12.7% (Very common)
Injection site oedema/swelling	11.3% (Very common)	10.3% (Very common)
Injection site bruising/ecchymosis	4.0% (Common)	4.1% (Common)
Injection site pruritus*	11.3% (Very common)	7.3% (Common)
Systemic complaints:		
Asthenia†	21.5% (Very common)	7.5% (Common)
Pyrexia (oral temperature > 38°C)	2.7% (Common)	3.4% (Common)
Rigors/Shivering	7.6% (Common)	4.2% (Common)
Malaise	12.6% (Very common)	8.8% (Common)
Nervous system disorders		
Headache	23.4% (Very common)	13.3% (Very common)
Musculoskeletal and connective tissue disorders		
Arthralgia†	7.3% (Common)	6.0% (Common)
Myalgia	20.9% (Very common)	11.6% (Very common)
Skin and subcutaneous tissue disorders		
Sweating increased†	9.0% (Common)	5.5% (Common)

* In adults, adverse reactions reported in 10/19 studies (3553 adults). In elderly, adverse reactions reported in 7/16 studies (4287 elderly).

† In adults, adverse reactions reported in 5/19 studies (1924 adults). In elderly, adverse reactions reported in 2/15 studies (201 elderly).

The table below summarises frequencies (weighted average from studies on the basis of study size) of unsolicited adverse reactions that were recorded within 21 days following vaccination in 2607 adults and 4597 elderly.

Table 3: Unsolicited adverse reactions within 21 days after vaccination of 7204 persons who received VAXIGRIP

Adverse reactions*	Adult 18-59 Years (N=2607)	Elderly ≥ 60 Years (N=4597)
General Disorders and Administration Site Conditions		
Local reactions:		
Injection site warmth	0.42% (Uncommon)	N/A
Injection site discomfort	0.12% (Uncommon)	N/A
Injection site pain	0.15% (Uncommon)	0.11% (Uncommon)
Injection site pruritus	0.18% (Uncommon)	0.13% (Uncommon)
Injection site induration	0.12% (Uncommon)	N/A
Systemic complaints:		
Flu-like illness	0.16% (Uncommon)	N/A
Blood and lymphatic system disorders		

Adverse reactions*	Adult 18-59 Years (N=2607)	Elderly ≥ 60 Years (N=4597)
Lymphadenopathy	0.23% (Uncommon)	0.07% (Rare)
Gastrointestinal disorders		
Diarrhoea	0.11% (Uncommon)	0.10% (Uncommon)
Nausea	0.30% (Uncommon)	N/A
Immune system disorders		
Pruritus	0.07% (Rare)	0.02% (Rare)
Pruritus generalised	0.03% (Rare)	N/A
Erythema	0.04% (Rare)	0.02% (Rare)
Generalised erythema	0.04% (Rare)	N/A
Rash	0.04% (Rare)	0.09% (Rare)
Urticaria	0.04% (Rare)	N/A
Swelling face	0.04% (Rare)	N/A
Nervous system disorders:		
Paraesthesia	0.08% (Rare)	0.02% (Rare)
Hypoesthesia	0.07% (Rare)	N/A
Somnolence	0.11% (Uncommon)	N/A
Dizziness	N/A	0.13% (Uncommon)
Neuralgia	N/A	0.02% (Rare)
Radiculitis brachial	N/A	0.02% (Rare)

N/A: Not Applicable according to the criteria used to select adverse reactions

* Unsolicited adverse reactions in this table were not reported in all the studies considered.

Paediatric population

In 6 clinical trials, 72 children/adolescents from 9 to 17 years, 460 children from 3 to 8 years and 54 children from 6 to 35 months received VAXIGRIP/VAXIGRIP Junior.

Depending on immunisation history, children from 6 months to 8 years received one or two doses of VAXIGRIP/VAXIGRIP Junior. Children from 6 to 35 months received the 0.25 ml formulation (VAXIGRIP Junior), and children from 3 years of age received the 0.5 ml formulation (VAXIGRIP).

- Children and adolescents

The table below summarises frequencies of solicited adverse reactions that were recorded within 3 days following vaccination in 5 studies. Data provided depends on the number of available studies and sample sizes:

- 34 children from 6 to 35 months (single study: GRT51; raw data)
- 440 children from 3 to 8 years (3 studies: GPF08, GQM02 and GRT52; weighted average)
- 72 children and adolescents from 9 to 17 years (2 studies: GQM04 and GPF08; range across individual trials)

Table 4: Solicited adverse reactions within 3 days after vaccination of 546 children and adolescents from 6 months to 17 years who received VAXIGRIP/VAXIGRIP Junior

Adverse reactions	Children and adolescents 9-17 years (N=72)	Children 3-8 years (N=440)	Children 6-35 months (N=34)
General Disorders and Administration Site Conditions			
<i>Local reactions:</i>			
Injection site pain/tenderness	54.5 to 70.6% (Very common)	44.2%* (Very common)	23.5% (Very common)
Injection site erythema/redness	5.5 to 17.6% (Very common)	20.9%* (Very common)	11.8% (Very common)
Injection site oedema/swelling	7.3 to 11.8% (Very common)	11.6%* (Very common)	5.9% (Common)
Injection site induration	5.9 to 7.3% (Common)	4.7%* (Common)	0%
Injection site bruising/ecchymosis	0 to 1.8% (Common)	4.5% (Common)	2.9% (Common)
Injection site pruritus	N/A	5.2% § (Common)	2.9% (Common)
<i>Systemic complaints:</i>			
Pyrexia	3.6 to 5.9% (Common)	9.3%* (Common)	20.6% (Very common)
Rigors	0 to 11.8% (Very common)	6.9%† (Common)	N/A
Malaise	5.9 to 14.5% (Very common)	20.3%† (Very common)	N/A
Metabolism and nutrition disorders			
Anorexia ¥	N/A	N/A	11.8% (Very common)
Psychiatric system disorders			
Irritability ¥	N/A	N/A	23.5% (Very common)
Crying abnormal ¥	N/A	N/A	20.6% (Very common)
Insomnia ¥	N/A	N/A	8.8% (Common)
Nervous system disorders			
Headache	21.8 to 23.5% (Very common)	10% ‡ (Very common)	N/A
Drowsiness ¥	N/A	N/A	11.8% (Very common)
Gastrointestinal disorders			
Vomiting ¥	N/A	N/A	2.9% (Common)
Diarrhoea ¥	N/A	N/A	14.7% (Very common)

Adverse reactions	Children and adolescents 9-17 years (N=72)	Children 3-8 years (N=440)	Children 6-35 months (N=34)
Musculoskeletal and connective tissue disorders Myalgia	12.7 to 17.6% (Very common)	10% ‡ (Very common)	N/A

¥ Adverse reactions only assessed in children from 6 to 35 months of age. In this age group, the other systemic adverse reactions are not solicited except for the fever

* Adverse reactions reported in 2/3 studies (86 children)

† Adverse reactions reported in 2/3 studies (364 children)

‡ Adverse reactions reported in 1/3 studies (10 children)

§ Adverse reactions reported in 1/3 studies (76 children)

The table below summarises the frequencies of the solicited adverse reactions that were recorded within 7 days following vaccination in 4 studies. Data provided depends on the number of available studies and sample sizes:

- 20 children from 6 to 35 months (single study: GID18; raw data)
- 384 children from 3 to 8 years (3 studies: GID18, GPF08 and GQM02; weighted average)
- 72 children and adolescents from 9 to 17 years (2 studies: GQM04 and GPF08; range across individual trials)

Table 5: Solicited adverse reactions within 7 days after vaccination of 476 children and adolescents from 6 months to 17 years who received VAXIGRIP/VAXIGRIP Junior

Adverse reactions	Children and adolescents 9-17 years (N=72)	Children 3-8 years (N=384)	Children 6-35 months (N=20)
General Disorders and Administration Site Conditions			
<i>Local reactions:</i>			
Injection site pain/tenderness	54.5 to 70.6% (Very common)	56.3% (Very common)	20% (Very common)
Injection site erythema/redness	5.5 to 17.6% (Very common)	23.4% (Very common)	25% (Very common)
Injection site oedema/swelling	7.3 to 11.8% (Very common)	19.6% (Very common)	15% (Very common)
Injection site induration	5.9 to 7.3% (Common)	14.6% (Very common)	15% (Very common)
Injection site bruising	0 to 1.8% (Common)	6.3% (Common)	N/A
<i>Systemic complaints:</i>			
Pyrexia	5.9 to 9.1% (Common)	7.3% (Common)	50% (Very common)

Adverse reactions	Children and adolescents 9-17 years (N=72)	Children 3-8 years (N=384)	Children 6-35 months (N=20)
Rigors	0 to 11.8% (Very common)	9%* (Common)	N/A
Malaise	11.8 to 16.4% (Very common)	27.3% (Very common)	N/A
Metabolism and nutrition disorders			
Decreased appetite ¥	N/A	N/A	35% (Very common)
Psychiatric system disorders			
Irritability ¥	N/A	N/A	60% (Very common)
Crying abnormal ¥	N/A	N/A	30% (Very common)
Nervous system disorders			
Headache	22.4 to 23.6% (Very common)	18.5% (Very common)	N/A
Drowsiness ¥	N/A	N/A	15% (Very common)
Gastrointestinal disorders			
Vomiting ¥	N/A	N/A	5% (Common)
Musculoskeletal and connective tissue disorders			
Myalgia	12.7 to 17.6% (Very common)	25.5% (Very common)	N/A

¥ Adverse reactions only assessed in children from 6 to 35 months of age. In this age group, the other systemic adverse reactions are not solicited except for the fever

* Adverse reactions reported in 2/3 studies (364 children)

The table below summarises frequencies of unsolicited adverse reactions that were recorded within 21 days* following vaccination in 5 clinical trials. Data provided depends on the number of available studies and sample sizes:

- 20 children from 6 to 35 months (single study: GRT51; raw data)
- 384 children from 3 to 8 years (3 studies: GID18, GPF08 and GQM02; weighted average)
- 72 children and adolescents from 9 to 17 years (2 studies: GQM04 and GPF08; range across individual trials)

Table 6: Unsolicited adverse reactions within 21 days† after vaccination of 476 children and adolescents who received VAXIGRIP/VAXIGRIP Junior

Adverse reactions *†	Children and adolescents 9-17 years (N=72)	Children 3-8 years (N=384)	Children 6-35 months (N=20)
General Disorders and Administration Site Conditions			
<i>Local reactions:</i>			
Injection site discomfort	0 to 1.8% (Common)	N/A	N/A
Injection site haemorrhage	N/A	0.26% (Uncommon)	N/A
Injection site warmth	0 to 5.9% (Common)	0.28% (Uncommon)	N/A
Injection site pruritus	0 to 1.8% (common)	N/A	N/A
Blood and lymphatic system disorders			
Lymphadenopathy	N/A	0.28% (Uncommon)	N/A
Immune system disorders			
Urticaria	N/A	0.46% (Uncommon)	N/A
Nervous system disorders:			
Dizziness	0 to 1.8% (Common)	N/A	N/A
Gastrointestinal disorders			
Diarrhoea	N/A	0.28% (Uncommon)	N/A

N/A: Not Applicable according to the criteria used to select adverse reactions

* Unsolicited adverse reactions in this table were not reported in all the studies considered.

† For some studies for which 1 or 2 doses were to be administered, unsolicited adverse events were collected 28 or 30 days after vaccination.

Data from Post-marketing experience

Based on spontaneous reporting, the following additional adverse events have been reported after commercial use (*). These events have been very rarely reported, however exact incidence rates cannot be calculated precisely so their frequency is qualified as “Not known”.

Blood and lymphatic system disorders

Transient thrombocytopenia, lymphadenopathy

Immune system disorders

Allergic reactions: pruritus, rash erythematous, urticaria, dyspnoea, angioedema, or shock

Nervous system disorders

Paraesthesia, Guillain-Barre Syndrome (GBS), neuritis, neuralgia, convulsions including febrile convulsions, encephalomyelitis.

Vascular disorders

Vasculitis, such as Henoch-Schonlein purpura, with transient renal involvement in certain cases.

(*) in some populations, some of these adverse events were reported during clinical trials.

DOSAGE AND ADMINISTRATION

Immunisation is normally undertaken in the autumn, in anticipation of winter outbreaks of influenza.

The vaccine should be administered by intramuscular or deep subcutaneous injection.

Table 7: Dosage recommendations

Age	Dose	No. of doses (first vaccination)	No. of doses⁽¹⁾ (subsequent years)
6 months to 35 months	0.25 mL	2*	1
3 to 8 years	0.5 mL	2*	1
≥ 9 years	0.5 mL	1	1

(1) Where children 6 months to ≤ 8 years of age receiving influenza vaccine for the first time have not received the second dose within the same year, they should be given 2 doses the following year.

* For children aged ≤ 8 years who are receiving influenza vaccine for the first time, it is recommended that they receive 2 doses at least 1 month apart.

When using the single dose 0.5 mL syringe for administering a 0.25 mL dose, push the plunger to the edge of the black mark on the glass syringe so that half of the volume is eliminated. Inject the remaining volume.

Parenteral drug products should be inspected visually for particulate matter and/or discolouration prior to administration whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

The contents of the syringe must be shaken thoroughly immediately before use. After shaking, the vaccine is a slightly whitish and opalescent liquid.

Syringes are for single use only and must not be used in more than one individual.

The current New Zealand Immunisation Handbook recommends that influenza vaccine can be administered concurrently with other vaccines, including pneumococcal polysaccharide vaccine and all the scheduled childhood vaccines. When administering VAXIGRIP concurrently with other vaccines, separate syringes and different injection sites should be used.

OVERDOSAGE

Cases of administration of more than the recommended dose (overdose) have been reported with VAXIGRIP. When adverse reactions were reported, the information

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was consistent with the known safety profile of VAXIGRIP described in ADVERSE EFFECTS.

For general advice on overdose management, contact the New Zealand National Poisons Centre on 0800 764 766.

PRESENTATION AND STORAGE CONDITIONS

Prefilled syringe containing 0.5 mL of vaccine.
Packs of 1 or 10 syringes

Store at 2°C to 8°C. (Refrigerate. Do not freeze). Protect from light.

NAME AND ADDRESS OF THE SPONSOR

New Zealand:
sanofi-aventis new zealand limited
Level 8
56 Cawley St
Ellerslie
Auckland
New Zealand
Tel: 0800 727 838

MEDICINES CLASSIFICATION

PRESCRIPTION ONLY MEDICINE

DATE OF PREPARATION

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