PRODUCT INFORMATION

NEISVAC-C®

NAME OF THE MEDICINE

Meningococcal group C polysaccharide conjugate vaccine (tetanus toxoid protein conjugate).

COMPOSITION

Active ingredient: each 0.5 mL dose contains 10 micrograms of meningococcal polysaccharide group C conjugated with 10 to 20 micrograms of tetanus toxoid protein, adsorbed to aluminium hydroxide (adjuvant).

Inactive ingredients: aluminium hydroxide (1.4 mg, equivalent to 0.5 mg aluminium), sodium chloride (4.1 mg) and water for injection to 0.5 mL. No preservative is added to the formulation.

CHEMICAL NAME

The capsular polysaccharide, referred to as GCMP (group C meningococcal polysaccharide) in NeisVac-C vaccine, is a linear polymer of repeated unit of [(2---9)-α-N-acetyl neuraminic acid; $(C_{11}H_{19}NO_9)_n$], with a defined molecular size. It is covalently bonded to a carrier protein, tetanus toxoid (TT).

DESCRIPTION

NeisVac-C vaccine is a sterile, homogenous semi-opaque white to off-white suspension filled in single dose syringes. It is supplied in a 1.0 mL pre-filled syringe (without an integrated needle), containing one deliverable 0.5 mL dose. Contains no antibacterial agent. Product is for single use in one patient only. Discard any residue.

The capsular polysaccharide is isolated from the fermentation of *Neisseria meningitidis* serogroup C (strain C11) The GCMP-TT Conjugate is devoid of an acetyl group at either C-7 or C-8 of the sialic acid (de-*O*-acetylated derivative). The oxidised GCMP intermediate is covalently bonded to TT protein by a reductive amination reaction, yielding the active ingredient, GCMP-TT conjugate.

The manufacturer of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be a human form of bovine spongiform encephalitis) has resulted from the administration of any vaccine product.

PHARMACOLOGY

Actions Immunology:

Neisseria meningitidis can cause severe systemic infections, including meningitis and septicemia. Vaccination with meningococcal polysaccharides induces the production of bactericidal antibodies that are serogroup specific. There are at least 13 serogroups, of which groups B and C are the most common. Infants below 2 years of age respond poorly to vaccination with unconjugated group C polysaccharide.

Through the protein component in the active ingredient, GCMP-TT Conjugate, the immune response to the polysaccharide antigen becomes T-cell dependent. By cooperation of T-cells and B-cells, the immune response toward the polysaccharide moiety is enhanced, particularly in younger children. Repeated administration of the polysaccharide-protein conjugate provides a good booster effect via an induction of cell memory. This is shown by the level of the IgG antibody after the first injection of GCMP-TT conjugate which continues to increase after the booster injection.

The un-conjugated homologue GCMP, like other polysaccharide antigens in these groups, divalent vaccine (groups A and C) and tetravalent vaccine (groups A, C, W_{135}, Y), are T-cell independent antigens. The B cells recognise the polysaccharide without the need of T-cell co-operation. However, the immune response is low, particularly in children younger than two years, who most need protection against invasive *Neisseria meningitidis*. Despite inducing protection in adults and older children that lasts at least 12 months, the antibody levels decline rapidly, and repeated vaccination fails to induce a booster effect.

CLINICAL TRIALS

All clinical studies with NeisVac-C vaccine were conducted in the United Kingdom, as summarised in Table 1. Over five completed Phase II clinical trials, the immunogenicity of NeisVac-C vaccine was evaluated in infants (n=83, aged 2 months), toddlers (n= 76, aged 12 –17 months), pre-school school children (n=310, 3.5 to <6 years of age), and school leavers (n= 319, 13 to 17 years of age). Phase III Clinical trials included children (n=1341, 4 – 18 years of age) and healthy infants (n=537, 6 – 11 weeks of age). Subjects achieving a fourfold rise in serum bactericidal activity (SBA) measured with infant rabbit complement (rSBA), rSBA titres >1: 8 , > 1: 16 and > 1 : 32, group C specific IgG titres >2 microgram/mL, and a fourfold rise in group C specific IgG titres from baseline to 3 – 5 weeks post vaccination with NeisVac-C vaccine were considered as a clinical success. The profile of the serum bactericidal titres of the age groups vaccinated with NeisVac-C vaccine during phase II clinical trials is shown in the Table 1.

Table 1: Phase II clinical trials: Immunogenicity Profiles

Serum bactericidal titres using infant rabbit complement (rSBA) of NeisVac-C vaccine in various age groups against meningococcal bacteria strain C11; bactericidal titre is defined as a reciprocal of the final dilution of sera that yields 50% killing or greater of the bacterial cells in 60 minutes. Blood samples were withdrawn 1 month after vaccination.

Subjects/ No. & Age	**Subjects with > 2ug/mL IgG (%)**	**Subjects with rSBA (> 1 : 16) (%)**	**(>1 : 32) (%)**	**Subjects with > 4 fold rise in rSBA (%)**	**rSBA (GMT#)**	**Dose schedule (single dose, except infant 3 doses)**
Infants (n = 83, 2 months)	71/71 (100%)	70/71(99%)	68/71 (96%)	65/68 (96%)	320.45	1st dose (2 months)
	79/79 (100%)	79/79(100%)	78/79 (99%)	71/74 (96%)	773.33	2nd dose(3 months)
	75/75 (100%)	75/75 (100%)	75/75 (100%)	68/69 (99%)	1062.56	3rd dose (4months)
	-	24/24 (100%)	24/24 (100%)	36/37 (97%)	1575	Booster dose (12 – 13 months) (0.5mL IM inject)
Toddlers (n = 76, 12 – 17 months)	61/62 (98.4%)	71/72(98.6%)	70/72 (97.2%)	72/72 (100%)	563.7	Single dose, IM inject. (0.5mL)[with MMR vaccine]
Pre-school (n = 310, 3.5 – 6 years)	144/150 (96.1%)	71/72 (100%)	71/72 (100%)	50/52 (100%)	2,098.0	Single dose, IM inject. (0.5mL) [with Tet-diphth Vaccine]
School leavers (n = 319, 13 – 17 years)	100/100 (100%)	12/12 (100%)	12/12 (100%)	12/12 (100%)	5486	Single dose, IM inject. (0.5mL), [with Tet-diphth. Vaccine]
Adults (n = 30, 18-upward)	30/30 (100%)	–	30/30 (100%)	30/30 (100%)	1730	Single dose, IM inject. (0.5mL)

GMT=Geometric Mean Titre.

Instead of human complement, rabbit complement was used in the SBA assays. The results were not directly comparable to that of SBA assays where human complement was used. However, a strong correlation was routinely observed between GCMP-specific IgG and SBA responses using rabbit complement for both adult and infant sera. Rabbit complement resulted in bactericidal titres averaging 4.4-fold higher than those seen using human complement. Thus, the original protective SBA threshold titre of 1: 4 with human complement would therefore translate to 1:16 or 1:32 dilution when using rabbit complement. The SBA titres of > 32 were considered to indicate seroconversion.

Among infants aged 2 to 4 months vaccinated with NeisVac-C vaccine, 100% developed serum bactericidal titres of at least 1: 8, one month after the second dose of this vaccine and greater than 99% had titres of at least 1:32 final dilution of the test sera. A booster dose in the second year of life induces an anamnestic response (booster effect).

The immunogenicity of NeisVac-C vaccine was compared with that of other conjugated group C meningococcal vaccines in 226 children aged 12-18 months in a published study conducted by the UK Public Health Laboratory Service. One month after the vaccines were given 82 – 97% of children had SBA titres >1:32, 91-100% had titres >1:8 and 89 – 100% had a > 4 fold increase in SBA titre. NeisVac-C vaccine induced higher SBA GMTs ($p<0.001$) and higher proportions of SBA > 1:8 ($p=0.02$) than did the MCC-CRM_{197} protein conjugates.

Protective Efficacy:

There have been no protective efficacy studies conducted with NeisVac-C vaccine. Three conjugated group C meningococcal vaccines, including NeisVac-C vaccine, are in use in the UK.

Surveillance data from England (Trotter C, et al. Effectiveness of memingococcal serogroup C conjugate vaccine 4 years after introduction. Lancet 2004; 364:365-67) is shown in the Table 2 below.

Table 2: Meningococcal group C conjugate vaccines[#]: effectiveness in immunized Cohorts, 4 years surveillance data.

Age at vaccination	Doses schedule*	Period of observation to Q1 2004 from:	Within 1 year of scheduled vaccination[¶]		More than 1 year after scheduled vaccination[¶]	
			Cases (Vaccinated)	% Vaccine effectiveness (95% CI)	Cases (vaccinated)	% Vaccine effectiveness (95% CI)
2 - 4 months	3	Q1 2000 -	9 (3)	93 (67 to 99)	19 (18)	-81 (-7430 to 71)
5 – 11 months	2	Q3 2000 -	6 (2)	87 (11 to 99)	7 (3)	82 (-8 to 97)
1 – 2 years	1	Q3 2000 -	19 (6)	88 (65 to 96)	6 (4)	61 (-327 to 94)
3 – 10 years	1	Q3 2000 -	45 (1)	98 (90 to 100)	19 (4)	93 (78 to 98)
11 – 18 years	1	Q2 2000 -	45 (4)	96 (89 to 99)	39 (8)	90 (77 to 96)
Total			124 (16)		90 (37)	

Note: # All commercial vaccines in the UK market were included in the surveillance. Q = Quarter; *Vaccine effectiveness compares children eligible for complete vaccination who had received all scheduled doses versus no doses. Partly vaccinated children were excluded; [¶] For the time change analysis, the three cohorts (3 – 4 year old, 4 – 6 year old and 7 – 10 year old) were combined, as were the 11 –16 year old and 17 – 18 year old cohorts.

INDICATIONS

NeisVac-C vaccine is indicated for active immunisation of children from 8 weeks of age, adolescents and adults, for the prevention of invasive disease caused by *Neisseria meningitidis* serogroup C.

CONTRAINDICATIONS

As with all vaccines, NeisVac-C vaccine is contraindicated in subjects with severe acute febrile illness. This vaccine should not be administered to subjects with known hypersensitivity to any component of the vaccine, including Tetanus Toxoid (TT), or to subjects having shown signs of hypersensitivity after previous administration of NeisVac-C vaccine.

PRECAUTIONS

As with all vaccines administered by injection, allergic reactions, including anaphylaxis, may occur after administration of NeisVac-C. Adequate medical treatment and provisions should be available for immediate use in the rare event of an anaphylactic reaction.

Avoid accidental intravascular administration which may lead to severe hypersensitivity reactions.

No data are available on subcutaneous administration of NeisVac-C vaccine; therefore, a possibility of any toxicity or reduced efficacy is unknown. NeisVac-C vaccine has been assessed only after intramuscular administration.

NeisVac-C vaccine confers protection specific to *Neisseria meningitidis* group C. Immunisation does not protect against other sero-groups or against meningitis or septicaemia caused by other organisms. The vaccine is not able to cause meningococcal C meningitidis. As with many vaccines, protection may not be conferred in 100% of patients. Therefore, clinical alertness to the possibility of co-incidental meningitidis should be maintained. In the event of clinical symptoms consistent with an invasive meningococcal infection (including petechiae and/or purpura) following vaccination, the aetiology should be thoroughly investigated.

Because of the risk of bleeding or haematoma at the injection site, benefits and risks should be carefully weighed when considering use of the vaccine in individuals with any coagulation disorder (eg. thrombocytopaenia) or concomitant anticoagulant therapy.

In individuals with impaired immune responsiveness (eg. due to use of immunosuppressive therapy, a genetic defect or HIV infection) this vaccine may not induce protective antibody levels following vaccination. Hence, vaccination may not result in an appropriate protective antibody response in all individuals.

The decision to administer or delay vaccination because of a current or recent acute clinical condition (with or without fever) depends largely on the severity of symptoms and their aetiology. Although a severe or even moderate febrile illness is sufficient reason to postpone vaccinations as the condition could be aggravated by adverse reactions to the vaccine or could impair the interpretation of possible vaccine adverse reactions, minor illness, such as mild respiratory infections with or without low-grade fever, are not generally contraindications.

The duration of antibody persistence beyond 6-8 months following vaccination with NeisVac-C vaccine and the duration of protection from invasive disease caused by *Neisseria meningitidis* are currently unknown. The need and appropriate time for revaccination are not currently known.

Immunisation with this vaccine is not a substitute for routine tetanus immunisation.

Inactivated vaccines and live vaccines, particularly those in the childhood schedule, can be given during the same visit but in different limbs.

Use in pregnancy (Category B2):

There is no adequate data in pregnant woman thus the safety of vaccine during pregnancy has not been established. The vaccine should not be used during pregnancy unless there is a defined risk of meningococcal C disease, in which case, the risk – benefit relationship should be evaluated.

Use in lactation:

Safety in lactation has not been established. It is not known whether NeisVac-C enters breast milk. Use this product in a nursing woman only when it is clearly needed and the potential benefit outweighs the potential risks to the baby.

Paediatric Use:

The potential risk of apnoea and the need for respiratory monitoring for 48 – 72h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity.

As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Use in the elderly:

There are no data on the use of Neisvac-C in adults aged 65 years or older.

Carcinogenicity/Genotoxicity/ Effects on fertility:

The carcinogenic and mutagenic potential of the active ingredient in NeisVac-C vaccine has not been evaluated. The effects of NeisVac-C on fertility have also not been established.

INTERACTIONS WITH OTHER MEDICINES

It is accepted that NeisVac-C vaccine can be administered simultaneously with other routine paediatric vaccines as long as separate sites and separate syringes are used. That is, oral polio vaccine (OPV), inactivated polio vaccine (IPV), diphtheria, tetanus and the whole cell or acellular pertussis-containing vaccines (eg. DPT, Td, DT), *Haemophilus influenzae* tetanus toxoid conjugate vaccines (Hib-TT), and measles, mumps and rubella vaccine (MMR). NeisVac-C must not be mixed with other vaccines in the same syringe.

The observed immune responses to co-administered vaccines have been satisfactory in:

- infants in studies in which NeisVac-C has been co-administered with a 7-valent or 10-valent pneumococcal conjugate vaccine;
- toddlers in a study in which NeisVac-C has been co-administered with a 7-valent pneumococcal conjugate vaccine;
- infants in a study in which NeisVac-C has been co-administered with a 13-valent pneumococcal conjugate vaccine.

Concomitant administration of NeisVac-C with PRP-OMP brand *Haemophilus influenzae* type b vaccine has not been adequately studied. However, concomitant use should only be considered if medically important.

Co-administration of NeisVac-C (2-dose infant schedule) and Infanrix Hexa vaccine (DTaP-IPV-HBV-Hib) in a 3-dose primary series in infants did not indicate any clinically relevant interference with responses to any of the antigens in the hexavalent vaccine.

Clinical studies in which NeisVac-C vaccine was given at the same time as, but at a different site from, OPV, DTP and Hib (infant schedule), MMR (one year schedule), DT (pre-school booster) and Td (school leavers) showed no increase in adverse reactions as a result of concomitant administration.

ADVERSE EFFECTS

The following adverse reactions have been identified from clinical studies conducted with NeisVac-C in infants (≤12 months of age), toddlers (12 months to 17 months of age), children (3.5 years to 18 years of age), and adults.

Clinical Trial Adverse Reactions							
System Organ Class (SOC)	ADR Term	Infants and/or Toddlers		Children		Adults	
		Frequency Category	Number of Patients (%) N = 1266	Frequency Category	Number of Patients (%) N = 1911	Frequency Category	Number of Patients (%) N = 130
INFECTIONS AND INFESTATIONS	Pharyngitis/ Rhinitis	Common	29 (2.29%)	Common	151 (9.21%)	-	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Lymphadenopathy	-	-	Uncommon	8 (0.42%)	Uncommon	1 (0.77%)
IMMUNE SYSTEM DISORDERS	Hyper-sensitivity reaction (incl. bronchospasm)	Rare	1 (0.08%)	Uncommon	11 (0.57%)	-	-
METABOLISM AND NUTRITION DISORDERS	Decreased appetite	Very common	495 (39.10%)	Uncommon	12 (0.63%)	-	-
PSYCHIATRIC DISORDERS	Sleep disorder (impaired sleeping)	Common	39 (3.08%)	-	-	-	-
	Agitation/ Restlessness	Common	40 (3.16%)	Uncommon	2 (0.10%)	-	-
NERVOUS SYSTEM DISORDERS	Convulsion	-	-	Uncommon	2 (0.10%)	-	-
	Sensory abnormalities (i.e., Paresthesia, Burning sensation, Hypoesthesia)	-		Uncommon	13 (0.68%)	-	-
	Syncope	-	-	Uncommon	6 (0.31%)	-	-
	Dizziness	-	-	Common	36 (1.88%)	-	-
	Sedation/ Somnolence	Very common	207 (16.35%)	Common	26 (1.36%)	-	-
	Headache	-	-	Very common	279 (14.6%)	Very common	16 (12.31%)
	Crying	Very common	368 (29.07%)	Uncommon	5 (0.26%)	-	-
EYE DISORDERS	Eyelid oedema	Rare	1 (0.08%)	Uncommon	2 (0.10%)	-	-

Clinical Trial Adverse Reactions							
VASCULAR DISORDERS	Circulatory collapse	Rare	1 (0.08%)	Rare	1 (0.05%)	-	-
	Flushing	Uncommon	2 (0.16%)	Uncommon	6 (0.31%)	-	-
RESPIRATORY DISORDERS	Cough	Common	17 (1.34%)	Common	42 (2.20%)	-	-
	Nasal congestion	-	-	Uncommon	6 (0.31%)	-	-
GASTRO-INTESTINAL DISORDERS	Vomiting	Very common	293 (23.14%)	Common	30 (1.57%)	Common	2 (1.54%)
	Diarrhoea	Common	70 (5.53%)	Common	20 (1.05%)	-	-
	Abdominal pain	Uncommon	7 (0.55%)	Common	64 (3.35%)	-	-
	Nausea	-	-	Common	99 (5.18%)	-	-
	Dyspepsia	Uncommon	9 (0.71%)	-	-	-	-
SKIN AND SUB-CUTANEOUS TISSUE DISORDERS	Rash	Common	32 (2.53%)	Uncommon	3 (0.16%)	-	-
	Pruritus	-	-	Common	44 (2.30%)	-	-
	Erythema	Uncommon	4 (0.32%)	-	-	-	-
	Hyperhidrosis	Common	18 (1.42%)	Uncommon	7 (0.37%)	-	-
	Dermatitis	-	-	Common	26 (1.36%)	-	-
	Ecchymosis	Rare	1 (0.08%)	Common	39 (2.04%)	-	-
MUSCULO-SKELETAL AND CONNECTIVE TISSUE DISORDERS	Myalgia	-	-	Uncommon	6 (0.31%)	Common	2 (1.54%)
	Arthralgia	-	-	Uncommon	5 (0.26%)	-	-
	Musculoskeletal stiffness (incl. neck stiffness, joint stiffness)	Rare	1 (0.08%)	Uncommon	18 (0.94%)	-	-
	Neck pain	-	-	Uncommon	10 (0.52%)	-	-
	Pain in extremity	Uncommon	3 (0.24%)	Common	108 (5.65%)	-	-
	Back pain	-	-	Uncommon	3 (0.16%)	-	-
GENERAL DISORDERS AND ADMIN-ISTRATION SITE CONDITIONS	Injection site reactions, including: Injection site tenderness/ pain Injection site swelling Injection site	 Very common Very common	 197 (15.56%) 134 (10.58%)	 Very common Very common	 1145 (59.92%) 465 (24.33%)	 Very common Very common	 109 (83.85%) 26 (20.00%)

Clinical Trial Adverse Reactions							
	erythema	Very common	283 (22.35%)	Very common	639 (33.44%)	Very common	40 (30.77%)
	Fever	Very common	277 (21.88%)	Common	80 (4.19%)	Common	3 (2.31%)
	Peripheral oedema	Uncommon	8 (0.63%)	Uncommon	5 (0.26%)	-	-
	Fatigue	Very common	379 (29.94%)	Common	49 (2.56%)	-	-
	Malaise	Uncommon	6 (0.47%)	Common	57 (2.98%)	Common	6 (4.62%)
	Chills	Uncommon	2 (0.16%)	Uncommon	6 (0.31%)	-	-
	Irritability	Very common	825 (65.17%)	Uncommon	15 (0.78%)	-	-
	Influenza-like illness	-	-	Rare	1 (0.05%)	Uncommon	1 (0.77%)
	Asthenia	-	-	Uncommon	8 (0.42%)	-	-

Legend: ADR frequency is based upon the following scale: Very Common (≥ 1/10); Common (≥ 1/100 - < 1/10), Uncommon (≥ 1/1,000 - < 1/100), Rare (≥ 1/10,000 - < 1/1,000), Very Rare (< 1/10,000)

Adverse Reactions from Post-Marketing Surveillance (for all age groups):

These frequencies are based on spontaneous reporting rates and have been calculated using number of reports and number of doses distributed.

***Blood and Lymphatic System Disorders*:**

Idiopathic thrombocytopaenic, purpura, lymphadenopathy.

***Immune System Disorders*:**

Anaphylaxis, hypersensitivity reactions (including bronchospasm), facial oedema and angioedema.

Metabolism and Nutrition Disorders:

Decreased appetite.

Psychiatric Disorders:

Sleep disorder (including impaired sleeping).

***Nervous System Disorders*:**

Dizziness, convulsions including febrile convulsions, sensory abnormalities (including hypoesthesia, paraesthesia and burning sensation), hypotonic-hyporesponsive episode, syncope, meningism, hypersomnia.

There have been very rare reports on seizures following meningococcal group C conjugate vaccines administration. Individuals usually recover rapidly. Some of the reported seizures may have been syncope. The reporting rate of seizures was below the background rate of epilepsy in children. In infants seizures were usually associated with fever and were likely to be febrile convulsions.

Respiratory, Thoracic and Mediastinal Disorders:

Dyspnoea, wheezing, nasal congestion, apnoea in very premature infants (≤ 28 weeks of gestation).

Gastrointestinal Disorders:

Nausea.

***Skin and Subcutaneous Tissue Disorders*:**

Rash (including maculovesicular rash, vesicular rash, maculopapular rash, papular rash, rash macular, heat rash, rash erythematosus, rash generalized, rash pruritic), urticaria, petechiae, purpura, erythema, Stevens-Johnson syndrome and erythema multiforme.

***Musculoskeletal, Connective Tissue and Bone Disorders*:**

Musculoskeletal stiffness (including neck stiffness, joint stiffness), neck pain, pain in extremity.

General Disorders and Administration Site Conditions:

Peripheral oedema, asthenia, fatigue, chills.

Class Reactions:

Relapse of nephrotic syndrome has been reported in association with administration of meningococcal group C conjugate vaccines in children.

DOSAGE AND ADMINISTRATION

General:

NeisVac-C vaccine is a sterile suspension in water for injection; thus, upon storage a white deposit and clear supernatant can be observed. The vaccine should be shaken thoroughly in order to obtain a homogenous suspension. After shaking, the vaccine should be a homogeneous semi-opaque white to off-white suspension**.** It should be inspected visually for particulate matter and discolouration prior to administration

whenever solution and container permit. In the event of either being observed, discard the vaccine, including the needle and syringe appropriately.

Dosage:

Infants under the age of 12 months: Two separate injections of 0.5 mL, the first dose given not earlier than 8 weeks of age and with interval of at least two months between doses.

Children, 12 months of age and older: a single dose of 0.5 mL

Adults and adolescent: a single dose of 0.5 mL

Booster dose: Estimates of MnCC vaccine effectiveness, from England's routine immunisation programme, have demonstrated the need for a booster dose after an infant primary series administered under the age of 12 months. A single booster dose should be given in the second year of life.

At present numbers of subject are too small to make a recommendation regarding a booster dose for toddlers who have received a single priming dose.

Effectiveness in all other groups (up to 18 years), primed with a single dose, has, in four years of surveillance, remained ≥ 90% – both within and more than one year after scheduled vaccination.

Non-conjugated meningococcal polysaccharide vaccines should not be used for booster vaccination as they may negatively influence the immunologic memory.

Method of administration:

NeisVac-C vaccine is for intramuscular use only, preferably in the anterolateral thigh region in infants and the deltoid region in older children, adolescent and adults. The vaccine must not be administered subcutaneously or intravenously.

In children 12 to 24 months of age, the injection of the vaccine may be made in the deltoid or the anterolateral thigh region.

The administration of the vaccine should be documented by the physician, and the lot number recorded**.**

OVERDOSAGE

There is no overdose experience with NeisVac-C vaccine. Overdosing with this vaccine is highly unlikely, as it is administered as a single-dose syringe by a health professional. If doses are administered closer together than recommended or more doses than required are administered, undesirable effects may occur.

PRESENTATION AND STORAGE CONDITIONS

NeisVac-C vaccine is presented as a semi-opaque white to off-white suspension in a single dose Type 1 (EP) glass syringe with a grey, isoprene bromobutyl tip cap and grey, bromobutyl rubber plunger stopper (Type 1, EP). The stopper and tip cap are latex free.

Pack size:

1's, 10's (2 x 5 trays) and 20's (2 x 10 trays). Not all pack sizes would be marketed.

Storage:

NeisVac-C vaccines should be stored at 2 ºC to 8 ºC (in a refrigerator). Do not freeze.

Can be stored at room temperature (≤ 25 °C) for a single period up to 9 months within the shelf life. When it is stored at room temperature, the initial date must be recorded and counted for a maximum of 9 months shelf life. At the end of this period the product should be used or discarded.

Shelf life:

42 months stored at 2 ºC to 8 ºC (in a refrigerator). Within this shelf life NeisVac-C can be stored at 25 ºC (room temperature) for a single period of up to 9 months and the product must not be returned to the refrigerator. *Contains no antibacterial agent. Product is for single use in one patient only. Discard any residue.* Upon storage a white deposit and clear supernatant can be observed. The expiry date of the vaccine is shown on the label and packaging.

Incompatibilities:

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

NAME AND ADDRESS OF THE SPONSOR

Pfizer Australia Pty Ltd
ABN 5000 8422 348
38-42 Wharf Road
WEST RYDE NSW 2114.

POISON SCHEDULE OF THE MEDICINE

Prescription only medicine (S4)

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG):

22 August 2002

DATE OF MOST RECENT AMENDMENT:

22 September 2015

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