SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

NIMENRIX (Meningococcal groups A, C, W-135 and Y conjugate vaccine) powder and solvent for solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

After reconstitution, 1 dose (0,5 mL) contains:

Neisseria meningitidis group A polysaccharide[1]	5 micrograms
Neisseria meningitidis group C polysaccharide[1]	5 micrograms
Neisseria meningitidis group W-135 polysaccharide[1]	5 micrograms
Neisseria meningitidis group Y polysaccharide[1]	5 micrograms
[1]conjugated to tetanus toxoid carrier protein	44 micrograms

Contains sugar (sucrose)

Excipients with known effect

Each 0,5 mL dose contains 28 mg of sucrose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

The powder or cake is white.

The solvent is clear and colourless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NIMENRIX is indicated for active immunisation of individuals from 6 weeks of age against invasive meningococcal disease caused by Neisseria meningitidis groups A, C, W-135, and Y.

4.2 Posology and method of administration

Posology

NIMENRIX should be used in accordance with available official recommendations.

Primary immunisation

Infants from 6 weeks to less than 6 months of age:

Two doses, each of 0,5 mL, should be administered with an interval of 2 months between doses.

Infants from 6 months of age, children, adolescents and adults:

A single 0,5 mL dose should be administered.

An additional primary dose of NIMENRIX may be considered appropriate for some individuals (see section 4.4).

Booster doses

Long-term antibody persistence data following vaccination with NIMENRIX are available up to 10 years after vaccination (see sections 4.4 and 5.1).

After completion of the primary immunisation course in infants 6 weeks to less than 12 months of age, a booster dose should be given at 12 months of age with an interval of at least 2 months after the last NIMENRIX vaccination (see section 5.1).

In previously vaccinated individuals 12 months of age and older, NIMENRIX may be given as a booster dose if they have received primary vaccination with a conjugated or plain polysaccharide meningococcal vaccine (see sections 4.4 and 5.1).

Method of administration

For intramuscular injection only.

In infants, the recommended injection site is the anterolateral aspect of the thigh. In individuals from 1 year of age, the recommended injection site is the anterolateral aspect of the thigh or the deltoid muscle (see sections 4.4 and 4.5).

For instructions on reconstitution of the vaccine before administration, see section 6.6.

4.3 Contraindications

NIMENRIX is contraindicated in patients who are hypersensitive to any of the active substances listed in section 2 or to any of the excipients of NIMENRIX listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicines, the name and the batch number of

the administered vaccine should be clearly recorded.

NIMENRIX should under no circumstances be administered intravascularly, intradermally or subcutaneously.

It is good clinical practice to precede vaccination by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable effects) and a clinical examination.

Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Intercurrent illness

Vaccination with NIMENRIX should be postponed in individuals suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Syncope

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from fainting.

Thrombocytopenia and coagulation disorders

NIMENRIX should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these

individuals.

Immunodeficiency

It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate immune response may not be elicited.

Persons with familial complement deficiencies (for example, C5 or C3 deficiencies) and persons receiving treatments that inhibit terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by Neisseria meningitidis groups A, C, W-135 and Y, even if they develop antibodies following vaccination with NIMENRIX.

Protection against meningococcal disease

NIMENRIX will only confer protection against Neisseria meningitidis groups A, C, W-135 and Y. The vaccine will not protect against any other Neisseria meningitidis groups.

A protective immune response may not be elicited in all vaccinees.

Effect of prior vaccination with plain polysaccharide meningococcal vaccine

Individuals previously vaccinated with a plain polysaccharide meningococcal vaccine and vaccinated with NIMENRIX 30 to 42 months later had lower Geometric Mean Titres (GMTs) measured with a serum bactericidal assay using rabbit complement (rSBA) than individuals who had not been vaccinated with any meningococcal vaccine in the preceding 10 years (see section 5.1). The clinical relevance of this observation is unknown.

Effect of pre-vaccination antibody to tetanus toxoid

The safety and immunogenicity of NIMENRIX was evaluated when it was sequentially administered or co-administered with a vaccine containing diphtheria and tetanus toxoids, acellular pertussis, inactivated polioviruses (1, 2 and 3), hepatitis B surface antigen and Haemophilus influenzae type b polyribosyl ribose phosphate conjugated to tetanus toxoid (DTaP-HBV-IPV/Hib) in the second year of life. The administration of NIMENRIX one month after the DTaP-HBV-IPV/Hib vaccine resulted in lower rSBA GMTs against groups A, C and W-135 compared with co-administration (see section 4.5). The clinical relevance of this observation is unknown.

Immune response in infants 6 months to less than 12 months of age

A single dose administered at 6 months of age was associated with lower human complement serum bactericidal assay (hSBA) titres to groups W-135 and Y compared with three doses administered at 2, 4, and 6 months of age (see section 5.1). The clinical relevance of this observation is unknown. If an infant 6 months to less than 12 months of age is expected to be at particular risk of invasive meningococcal disease due to exposure to groups W-135 and/or Y, consideration may be given to administering a second primary dose of NIMENRIX after an interval of 2 months.

Immune responses in toddlers 12 - 14 months of age

Toddlers aged 12 - 14 months had similar rSBA titres to groups A, C, W-135 and Y at one month after one dose of NIMENRIX or at one month after two doses of NIMENRIX given two months apart.

A single dose was associated with lower hSBA titres to groups W-135 and Y compared with two doses given two months apart. Similar responses to groups A and C were observed after one or two doses

(see section 5.1). The clinical relevance of this observation is unknown. If a toddler is expected to be at particular risk of invasive meningococcal disease due to exposure to groups W-135 and/or Y, consideration may be given to administering a second dose of NIMENRIX after an interval of 2 months. Regarding the waning of antibodies against group A or group C after a first dose of NIMENRIX in children 12 - 23 months of age, see section Persistence of serum bactericidal antibody titres.

Persistence of serum bactericidal antibody titres

Following administration of NIMENRIX there is a waning of serum bactericidal antibody titres against group A when using hSBA (see section 5.1). The clinical relevance of this observation is unknown. However, if an individual is expected to be at particular risk of exposure to group A and received a dose of NIMENRIX more than approximately one year previously, consideration may be given to administering a booster dose.

A decline in antibody titres over time has been observed for groups A, C, W-135 and Y. The clinical relevance of this observation is unknown. A booster dose might be considered in individuals vaccinated at toddler age remaining at high risk of exposure to meningococcal disease caused by groups A, C, W-135 or Y (see section 5.1).

Effect of NIMENRIX on anti-tetanus antibody concentrations

Although an increase of the anti-tetanus toxoid (TT) antibody concentrations was observed following vaccination with NIMENRIX, NIMENRIX does not substitute for tetanus immunisation.

Giving NIMENRIX with or one month before a TT-containing vaccine in the second year of life does not impair the response to TT or significantly affect safety. No data are available beyond 2 years of age.

Sodium content

NIMENRIX contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

4.5 Interaction with other medicines and other forms of interaction

In infants, NIMENRIX can be given concomitantly with combined DTaP-HBV-IPV/Hib vaccines and with 10-valent pneumococcal conjugate vaccine.

From 1 year of age and above, NIMENRIX can be given concomitantly with any of the following vaccines: hepatitis A (HAV) and hepatitis B (HBV) vaccines, measles - mumps - rubella (MMR) vaccine, measles - mumps - rubella - varicella (MMRV) vaccine, 10-valent pneumococcal conjugate vaccine or unadjuvanted seasonal influenza vaccine.

In the second year of life, NIMENRIX can also be given concomitantly with combined diphtheria - tetanus - acellular pertussis (DTaP) vaccines, including combination DTaP vaccines with hepatitis B, inactivated poliovirus or Haemophilus influenzae type b (HBV, IPV or Hib) such as DTaP-HBV-IPV/Hib vaccine, and 13-valent pneumococcal conjugate vaccine.

In individuals 9 to 25 years of age, NIMENRIX can be given concomitantly with human papillomavirus bivalent [Type 16 and 18] vaccine, recombinant (HPV2).

Whenever possible, NIMENRIX and a TT containing vaccine, such as DTaP-HBV-IPV/Hib vaccine, should be co-administered or NIMENRIX should be administered at least one month before the TT containing vaccine.

One month after co-administration with a 10-valent pneumococcal conjugate vaccine, lower Geometric Mean antibody Concentrations (GMCs) and opsonophagocytic assay (OPA) antibody GMTs were observed for one pneumococcal serotype (18C conjugated to tetanus toxoid carrier protein). The clinical relevance of this observation is unknown. There was no impact of co-administration on immune responses to the other nine pneumococcal serotypes.

One month after co-administration with a combined tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed (Tdap) in individuals 9 to 25 years of age, lower GMCs were observed to each pertussis antigen (pertussis toxoid [PT], filamentous haemagglutinin [FHA] and pertactin [PRN]). More than 98 % of individuals had anti-PT, FHA or PRN concentrations above the

assay cut-off thresholds. The clinical relevance of these observations is unknown. There was no impact of co-administration on immune responses to NIMENRIX or the tetanus or diphtheria antigens included in Tdap.

If NIMENRIX is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

It may be expected that in patients receiving immunosuppressive treatment, an adequate response may not be elicited.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited experience with use of NIMENRIX in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3).

NIMENRIX should be used during pregnancy only when clearly needed, and the possible advantages outweigh the potential risks for the foetus.

Breastfeeding

It is unknown whether NIMENRIX is excreted in human milk.

NIMENRIX should only be used during breastfeeding when the possible advantages outweigh the potential risks.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to fertility

4.7 Effects on ability to drive and use machines

No studies on the effects of NIMENRIX on the ability to drive and use machines have been performed. However, some of the effects mentioned in Section 4.8 “Undesirable effects” may affect the ability to drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

The safety of NIMENRIX presented in the table below is based on two clinical study datasets as follows:

- A pooled analysis of data from 9 621 individuals administered a single dose of NIMENRIX.

This total included 3 079 toddlers (12 months to 23 months of age), 909 children between 2 and 5

years of age, 990 children between 6 and 10 years of age, 2 317 adolescents (11 to 17 years of age) and 2 326 adults (18 to 55 years of age).

- Data from a study in infants 6 to 12 weeks of age at the time of the first dose (Study MenACWY TT-083), 1 052 individuals received at least one dose of a primary series of 2 or 3 doses of NIMENRIX and 1 008 received a booster dose at approximately 12 months of age.

Safety data have also been evaluated in a separate study in which a single dose of NIMENRIX was administered to 274 individuals 56 years of age and older.

Local and general adverse reactions

In the 6 - 12 weeks and in the 12 - 14 months age groups who received 2 doses of NIMENRIX given 2 months apart, the first and second doses were associated with similar local and systemic reactogenicity.

The local and general adverse reaction profile of a booster dose of NIMENRIX given to individuals from 12 months through 30 years of age after primary vaccination with NIMENRIX or other conjugated or plain polysaccharide meningococcal vaccines, was similar to the local and general adverse reaction profile observed after primary vaccination with NIMENRIX, except for gastrointestinal symptoms (including diarrhoea, vomiting, and nausea), which were very common among individuals 6 years of age and older.

Tabulated summary of adverse reactions

Adverse reactions reported are listed according to the following frequency categories: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000); not known (cannot be estimated from available data).

Table 1 shows the adverse reactions reported from the studies in individuals from 6 weeks up to 55 years of age and post-marketing experience. Adverse reactions reported in individuals > 55 years of age were similar to those observed in younger adults.

Table 1: Tabulated summary of adverse reactions by system organ class

System organ class	**Frequency**	**Adverse reactions**
Metabolism and nutrition disorders	Very common	Loss of appetite

Psychiatric disorders	Very common	Irritability
	Uncommon	Insomnia, crying
Nervous system disorders	Very common	Drowsiness, headache
	Uncommon	Hypoaesthesia, dizziness
	Rare	Febrile convulsions
Gastrointestinal disorders	Common	Diarrhoea, vomiting, nausea*
Skin and subcutaneous tissue disorders	Uncommon	Pruritus, urticaria, rash**
Musculoskeletal and connective tissue disorders	Uncommon	Myalgia, pain in extremities
General disorders and administration site conditions	Very common	Fever, swelling at injection site, pain at injection site, redness at injection site, fatigue
	Common	Injection site haematoma*

	Uncommon	Malaise, injection site induration, injection site pruritus, injection site warmth, injection site anaesthesia

*Nausea and Injection site haematoma occurred at a frequency of Uncommon in infants

**Rash occurred at a frequency of Common in infants

Post-marketing adverse events

System organ class	**Side effect**
Blood and lymphatic system disorders	Lymphadenopathy
Immune system disorders	Hypersensitivity
	Anaphylaxis
General disorders and administration site conditions	Extensive limb swelling at the injection site frequently associated with erythema, sometimes involving the adjacent joint or swelling of the entire injected limb

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, meningococcal vaccines, ATC code: J07AH08

Mechanism of action

Anti-capsular meningococcal antibodies protect against meningococcal disease via complement mediated bactericidal activity. Meningococcal group acwy-tt conjugate vaccine induces the production of bactericidal antibodies against capsular polysaccharides of Neisseria meningitidis groups A, C, W-135 and Y when measured by assays using either rSBA or hSBA.

Immunogenicity in infants

In Study MenACWY-TT-083, the first dose was administered at 6 to 12 weeks of age, the second after an interval of 2 months, and a third (booster) dose administered at approximately 12 months of age. DTaP-HBV-IPV/Hib and a 10-valent pneumococcal vaccine were co-administered. Meningococcal group acwy-tt conjugate vaccine elicited rSBA and hSBA titres against the four meningococcal groups. The response against group C was non-inferior to the

one elicited by licensed MenC-CRM and MenC-TT vaccines in terms of percentages with rSBA titres ≥ 8 at 1 month after the second dose.

Data from this study support the extrapolation of the immunogenicity data and posology to infants from 12 weeks to less than 6 months of age.

In Study MenACWY-TT-087, infants received either a single primary dose at 6 months followed by a booster dose at 15 - 18 months (DTaP-IPV/Hib and 10-valent pneumococcal conjugate vaccine was co administered at both vaccination time points) or three primary doses at 2, 4, and 6 months followed by a booster dose at 15 - 18 months. A single primary dose administered at 6 months of age elicited robust rSBA titres, as measured by the percentage of individuals with rSBA titres ≥ 8 (94 – 99 %), to the four meningococcal groups, that were comparable to responses after the last dose of a three-dose primary series. A booster dose produced robust responses, comparable between the two dosing groups, against all four meningococcal groups.

Measurement of hSBA titres was a secondary endpoint in Study MenACWY-TT-087. Although similar responses to groups A and C were observed with both dosing schedules, a single primary dose in infants at 6 months was associated with lower hSBA titres to groups W-135 and Y as measured by the percentage of individuals with hSBA titres ≥ 8 (87 – 92 %) compared with three primary doses at 2, 4m and 6 months of age (100 %). After a booster dose, hSBA titres to all four meningococcal groups were comparable between the two dosing schedules.

Immunogenicity in toddlers aged 12 - 23 months

In clinical studies MenACWY-TT-039 and MenACWY-TT-040, a single dose of meningococcal group acwy-tt conjugate vaccine elicited SBA titres against the four meningococcal groups, with group C rSBA titres that were comparable to those elicited by a licensed MenC-CRM vaccine in

terms of the percentage of individuals with rSBA titres ≥ 8. In Study MenACWY-TT-039, hSBA was also measured as a secondary endpoint.

In Study MenACWY-TT-104, meningococcal group acwy-tt conjugate vaccine elicited rSBA titres against all four meningococcal groups following one or two doses administered 2 months apart that were similar in terms of the percentage of individuals with rSBA titre ≥ 8 and GMT.

In Study MenACWY-TT-104, hSBA titres were measured as a secondary endpoint. Meningococcal group acwy-tt conjugate vaccine elicited hSBA titres against groups W-135 and Y that were higher in terms of the percentage of individuals with hSBA titre ≥ 8 when two doses were given compared with one (see section 4.4). Meningococcal group acwy-tt conjugate vaccine elicited hSBA titres against groups A and C that were similar in terms of the percentage of individuals with hSBA titre ≥ 8 when two doses were given compared with one.

In Study MenACWY-TT-100, rSBA titres ≥ 8 were determined over a period of 10 years in children initially vaccinated with one dose of meningococcal group acwy-tt conjugate vaccine at 12 to 23 months of age in Study MenACWY-TT-027, immune response at 10 years pre-booster remained above baseline and post booster resulted in a 100 % for all 4 groups.

Persistence of booster response

In Study MenACWY-TT-102, rSBA titres ≥ 8 were determined up to 6 years after a booster dose of meningococcal group acwy-tt conjugate vaccine or MenC-CRM197 administered in Study MenACWY-TT-048 to children who initially received the same vaccine at 12 to 23 months of age in Study

MenACWY-TT-039. A single booster dose was administered 4 years after the initial vaccination, immune response post booster resulted in a 100 % and after 6 years remained above baseline for all 4 groups.

Immunogenicity in children aged 2 - 10 years

In Study MenACWY-TT-081, a single dose of meningococcal group acwy-tt conjugate vaccine was demonstrated to be non-inferior to another licensed MenC-CRM vaccine in terms of vaccine response to group C (95 – 96 %). The GMT was lower for the meningococcal group acwy-tt conjugate vaccine group [2795 (95 % CI: 2393; 3263)] versus the MenC-CRM vaccine [5292 (95 % CI: 3815; 7340)].

In Study MenACWY-TT-038, a single dose of meningococcal group acwy-tt conjugate vaccine was demonstrated to be non-inferior to the licensed ACWY PS vaccine in terms of vaccine response to the four meningococcal groups.

In Study MenACWY-TT-100, rSBA titres ≥ 8 were determined over a period of 10 years in children initially vaccinated with one dose of meningococcal group acwy-tt conjugate vaccine at 2 to 10 years of age in Study MenACWY-TT-027, immune response at 10 years pre-booster remained above baseline and post booster resulted in a 100 % for all 4 groups.

Immunogenicity in adolescents aged 11 - 17 years and adults aged ≥ 18 years

In two clinical studies, conducted in adolescents aged 11 - 17 years (Study MenACWY-TT-036) and in adults aged 18 - 55 years (Study MenACWY-TT-035), either one dose of meningococcal group acwy-tt conjugate vaccine or one dose of the ACWY-PS vaccine was administered.

Meningococcal group acwy-tt conjugate vaccine was demonstrated to be immunologically non-inferior to the ACWY-PS vaccine in terms of vaccine response.

In Study MenACWY-TT-101, rSBA titres ≥ 8 were determined over a period of 10 years in individuals initially vaccinated with one dose of meningococcal group acwy-tt conjugate vaccine at 11 to 17 years of age in Study MenACWY-TT-036, immune response at 10 years pre-booster remained above baseline and post booster resulted in a 100 % for all 4 groups.

In Study MenACWY-TT-099, rSBA titres ≥ 8 were determined over a period of 10 years in individuals initially vaccinated with one dose of meningococcal group acwy-tt conjugate vaccine at 11 to 55 years of age in Study MenACWY-TT-015, immune response at 10 years pre-booster remained above baseline and post booster resulted in a 100 % for all 4 groups.

In a separate study (MenACWY-TT-085), a single dose of meningococcal group acwy-tt conjugate vaccine was administered to 194 Lebanese adults aged 56 years and older (including 133 aged 56 - 65 years and 61 aged > 65 years). The percentage of individuals with rSBA titres ≥ 128 before vaccination ranged from 45 % (group C) to 62 % (group Y). Overall, at 1-month post-vaccination the

percentage of vaccines with rSBA titres ≥ 128 ranged from 93 % (group C) to 97 % (group Y). In the subgroup aged > 65 years the percentage of vaccines with rSBA titres ≥ 128 at 1-month post-vaccination ranged from 90 % (group A) to 97 % (group Y).

Booster response for individuals previously vaccinated with a conjugate meningococcal vaccine against Neisseria meningitidis

Meningococcal group acwy-tt conjugate booster vaccination in individuals previously primed with a monovalent (MenC-CRM) or a quadrivalent conjugate meningococcal vaccine (MenACWY-TT) was studied in individuals from 12 months of age onwards who received a booster vaccination. Robust anamnestic responses to the antigen(s) in the priming vaccine were observed.

Response to meningococcal group acwy-tt conjugate vaccine in individuals previously vaccinated with a plain polysaccharide vaccine against Neisseria meningitidis

In Study MenACWY-TT-021 conducted in individuals aged 4,5 - 34 years, the immunogenicity of meningococcal group acwy-tt conjugate vaccine administered between 30 and 42 months after vaccination with a ACWY-PS vaccine was compared to the immunogenicity of meningococcal group acwy-tt conjugate vaccine administered to age-matched individuals who had not been vaccinated with any meningococcal vaccine in the preceding 10 years. An immune response (rSBA titre ≥ 8) was observed against all four meningococcal groups in all individuals regardless of the meningococcal vaccine history. The rSBA GMTs were significantly lower in the individuals who had received a dose of ACWY-PS vaccine 30 - 42 months prior to meningococcal group acwy-tt conjugate vaccine, however

100 % of individuals achieved rSBA titres ≥ 8 for all four meningococcal groups (A, C, W-135, Y) (see section 4.4).

Children (2 - 17 years) with anatomical or functional asplenia

Study MenACWY-TT-084 compared immune responses to two doses of meningococcal group acwy-tt conjugate vaccine given 2 months apart between 43 individuals aged 2 - 17 years with anatomic or functional asplenia individuals and 43 age matched individuals with normal splenic function. One month after the first vaccine dose and 1 month after the second dose similar percentages of individuals in the two groups had rSBA titres ≥ 8 and hSBA titres ≥ 8.

Impact of a single dose of meningococcal group acwy-tt conjugate vaccine In 2018, the Netherlands added meningococcal group acwy-tt conjugate vaccine to the national immunisation programme as a single dose for toddlers at 14 months of age to replace the meningococcal C conjugate vaccine. A catch-up campaign with a single dose of meningococcal group acwy-tt conjugate vaccine for adolescents 14 - 18 years of age also initiated in 2018, and it became routine in 2020 leading to a toddler and adolescent national immunisation programme. Within two years, the incidence of meningococcal disease caused by groups C, W, and Y was significantly reduced by 100 % (95 % CI: 14, 100) in individuals 14 - 18 years of age, 85 % (95 % CI: 32, 97) in all vaccine eligible ages (direct effect), and 50 % (95 % CI: 28, 65) in non-vaccine eligible ages (indirect effect). The impact of meningococcal group acwy-tt conjugate vaccine was primarily driven by a reduction in group W disease.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder

Sucrose

Trometamol

Solvent

Sodium chloride

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, NIMENRIX must not be mixed with other medicines.

6.3 Shelf life

4 years.

After reconstitution

After reconstitution, NIMENRIX should be used promptly. Although delay is not recommended, stability has been demonstrated for 8 hours at 30 °C after reconstitution. If not used within 8 hours, do not administer the vaccine.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Store in the original package in order to protect from light.

For storage conditions after reconstitution of NIMENRIX, see section 6.3.

6.5 Nature and contents of container

White powder in a vial (type I glass) with a grey stopper (butyl rubber) and colourless solvent in a pre-filled syringe with a stopper (butyl rubber).

Pack sizes of 1 and 10 with or without needles.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

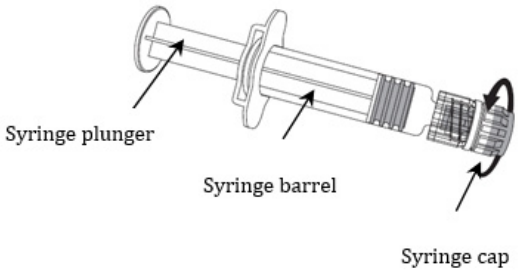
Instructions for reconstitution of the vaccine with the solvent presented in pre-filled syringe

NIMENRIX must be reconstituted by adding the entire content of the pre-filled syringe of solvent to the vial containing the powder.

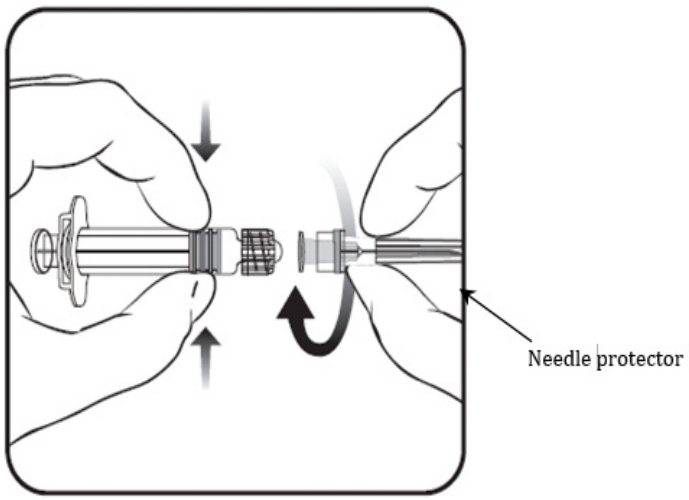
To attach the needle to the syringe, refer to the picture below. However, the syringe provided with NIMENRIX might be slightly different (without screw thread) than the syringe described in the picture.

In that case, the needle should be attached without screwing.

1. Holding the syringe barrel in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.



2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock (see picture)



3. Remove the needle protector, which on occasion can be a little stiff.
4. Add the solvent to the powder. After the addition of the solvent to the powder, the mixture should

be well shaken until the powder is completely dissolved in the solvent.

The reconstituted vaccine is a clear colourless solution.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccine.

After reconstitution, the vaccine should be used promptly.

A new needle should be used to administer the vaccine.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pfizer Laboratories (Pty) Ltd

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Midrand, Gauteng, 1685

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Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

8. REGISTRATION NUMBERS

57/30.2/0404

9. DATE OF FIRST AUTHORISATION

23 September 2025

10. DATE OF REVISION OF THE TEXT

To be advised