

Menjugate[®] Syringe

Meningococcal group C-CRM 197 conjugate vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Menjugate Syringe.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child having Menjugate Syringe against the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.
You may need to read it again.

What Menjugate Syringe is used for

Menjugate Syringe is a vaccine used to help prevent meningitis and/or septicaemia caused by the bacteria named *Neisseria meningitidis* serogroup C (also known as meningococcus C).

Menjugate Syringe is effective in persons from 6 weeks of age (infants, children and adults).

Meningitis results in the inflammation of the tissues surrounding the brain and/or spinal cord. Septicaemia is a poisoning of the blood.

Neisseria meningitidis can cause sudden serious and sometimes life-threatening illness, even in previously healthy persons.

Symptoms usually associated with meningitis are rash together with

any of the following: fever, vomiting, drowsiness, headache, stiff neck.

Meningitis is transmitted by droplets carried in the air from the nose and/or throat of infected persons. Only a small number of people carrying the meningococcal bacteria will become ill. Close contact with a person with meningitis will increase the chances of becoming infected.

Meningococcal disease occurs more commonly in winter and early spring.

Meningococcal disease can be caused by a number of different strains of *N. meningitidis*. Menjugate Syringe can only protect against one of these strains, serogroup C.

Menjugate Syringe cannot protect against other causes of meningitis and septicaemia.

How it works

Menjugate Syringe works by causing your body to produce its own protection against meningococcal group C disease. It does this by making substances called antibodies in the blood which fight *N. meningitidis* serogroup C. If a vaccinated person comes into contact with *N. meningitidis* serogroup C bacteria, the body is usually ready to destroy it.

Your body usually takes several weeks after vaccination to develop protection against *N. meningitidis* serogroup C.

Protection requires 2 doses in infants under the age of 12 months and 1 dose in persons over the age of 12 months. In order to maintain protection, it is recommended that a booster dose is given after the infant course of two doses has been completed. Your doctor will

advise you when your child should receive this.

Most people will produce enough antibodies against *N. meningitidis* serogroup C. However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine will not give you or your child meningitis. The chance of a severe reaction from Menjugate Syringe is very small, but the risks from not being vaccinated against *N. meningitidis* serogroup C disease may be very serious.

Before you are given Menjugate Syringe

When you or your child must not be given it

Do not have Menjugate Syringe if you have an allergy to:

Menjugate Syringe or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting

Menjugate Syringe is not recommended for use in children under 6 weeks of age.

Do not have Menjugate Syringe after the expiry date printed on the pack.

Do not have Menjugate Syringe if the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should have Menjugate Syringe, talk to your doctor or pharmacist.

Before you or your child are given it

Tell your doctor if you or your child have reacted to previous vaccination with any of the following:

- life-threatening allergic reaction (*anaphylaxis*)
- difficulty breathing (*bronchospasm*)
- swelling of the throat (*laryngeal oedema*)
- fainting or collapse (*generalised collapse*)
- shock-like state or being unresponsive for a long period of time (*hypotonic / hyporesponsive episode*)
- fits or convulsions (*convulsions*)
- high temperature
- crying or screaming lasting for more than 3 hours
- severe skin reaction at the injection site, including severe bruising (*thrombocytopenia*)

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

Tell your doctor if you have, or have had, any medical conditions, especially those listed below:

- lowered immunity due to diseases such as some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer (*agammaglobulinaemia, hypogammaglobulinaemia, malaria, renal dialysis, HIV infection, combined immunodeficiency, immunosuppressed patients, generalised malignancy*)
- lowered immunity due to treatment with medicines such as corticosteroids, or other medicines used to treat cancer -

including radiation therapy (*immunocompromised patients*)

- leukaemia or any other cancers of the blood, bone marrow or lymph system (*leukaemia, lymphoid tumours, lymphoma*)

In conditions resulting in lowered immunity you or your child's immune response may be lower than in individuals with healthy immune systems.

- allergies or allergic reactions, including: runny, blocked or itchy nose; itchy rash or hives; swelling of the face, lips, mouth or tongue (*allergy, allergic reactions, rhinitis, urticaria, angioedema*)
- a low blood platelet count (*thrombocytopenia*)
- blood clotting disorder (*for example haemophilia*)
- the kidney disease in which large amounts of protein appear in the urine (called *nephrotic syndrome*)

There have been reports of relapse of this condition after vaccination. Your doctor will advise you if you can still have Menjugate Syringe depending on the exact type of kidney problem you have.

If your child is a premature baby, take special care as longer gaps than normal between breaths may occur. Your doctor may decide to monitor your baby for at least 48 hours after vaccination especially if your baby is born before 28 weeks of pregnancy. As the benefit of vaccination is high in this group of infants, vaccination must not be withheld or delayed.

Tell your doctor if you have allergies to:

- any other medicines
- latex
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Menjugate Syringe is not recommended during pregnancy. If there is a need to consider vaccination during pregnancy, your doctor will discuss with you the benefits and risks of having it.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having Menjugate Syringe during breastfeeding.

Important information about some of the ingredients of Menjugate Syringe

The tip cap protecting the tip of the syringe contains 10% Dry Natural Rubber. Please tell your doctor if you (or your child) ever had an allergic reaction to latex.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Having other vaccines

Tell your doctor if you have had any vaccines in the last 4 weeks.

Your doctor will advise you if Menjugate Syringe is to be given with another vaccine.

Menjugate Syringe may be safely given at the same time, with other paediatric vaccinations given by mouth or by injection including, polio; measles, mumps, rubella (MMR); diphtheria and tetanus toxoids combined with whole cell or acellular pertussis vaccines; haemophilus influenzae (Hib) conjugate vaccines; hepatitis B (HBV) vaccine given alone or at the same time as a combined vaccine containing diphtheria, tetanus, Hib, inactivated polio and acellular pertussis; and 7-valent pneumococcal conjugate vaccine. The normal schedule of vaccination can be used but please remember that Menjugate Syringe should not be mixed with other vaccines in the same syringe. Separate injection sites should be used if more than one vaccine is being administered.

Your doctor and pharmacist may have more information on medicines and vaccines to avoid during vaccination with Menjugate Syringe.

How Menjugate Syringe is given

Menjugate Syringe is given as an injection, usually into the deltoid (upper arm) muscle by a doctor or nurse. For babies, Menjugate Syringe may be given into the anterolateral thigh (upper thigh) muscle.

Menjugate Syringe should not be injected directly into the bloodstream.

How much is given

The dose is 0.5 mL given by injection.

When it is given

The usual vaccination schedule is

Age group	No. of doses	Comment
Infants*	2	Start at 2 months of age; intervals of = 2 months
Children > 12 months	1	-
Adolescents	1	-
Adults	1	-

* It is recommended that vaccinated infants have a booster dose at or after 12 months of age.

If you miss a dose

If your infant misses a dose, talk to your doctor and arrange another visit as soon as possible.

After having Menjugate Syringe

Things you or your child must do

Keep an updated record of your vaccinations.

Keep follow-up appointments with your doctor or clinic.

As with all paediatric vaccines it is important that your infant receives their follow-up doses of Menjugate Syringe at the appropriate times.

Have any blood tests when your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how Menjugate Syringe affects you.

Menjugate Syringe should not normally interfere with your ability to drive or operate machinery. However, it may cause dizziness and/or faints in some people.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well after having Menjugate Syringe.

Menjugate Syringe may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects. **Ask your doctor or pharmacist to answer any questions you may have.**

The more common side effects of Menjugate Syringe are listed below. Mostly they are mild and short-lived.

If you notice any of the following and they worry you tell your doctor or pharmacist:

- redness, itchiness, tenderness, pain or discomfort, warmth, or swelling at the injection site (*localised reactions*)
- headaches (*headaches*)
- tiredness, weakness or fatigue (*fatigue*)
- generally feeling unwell (*malaise*)
- high temperature (*fever, chills*)
- soreness or aching muscles- not caused by exercise (*myalgia*)
- sleepiness (*sleepiness, somnolence*)
- irritability (*irritability*)
- difficulty sleeping (*insomnia*)
- unusual screaming or crying
- eating and drinking less than usual, loss of appetite (*fussing, diminished appetite, anorexia*)

- nausea or vomiting (*nausea, vomiting*)
- diarrhoea (*diarrhoea*)
- rash (*urticaria, pruritus*)
- pain in joints (*arthralgia*)

Tell your doctor immediately if you notice any of the following:

- skin rash or spots on the skin (*erythema*)
- painful, swollen joints (*arthralgia*)
- loss of muscle tone (*hypotonia*)
- swelling of the glands in the neck, armpit or groin (*regional lymphadenopathy*)
- itchiness, hives or rash over the body (*urticaria, pruritus*)
- severe dizziness, unsteadiness when walking or spinning sensation, faints (*vertigo*)
- fits or convulsions (*convulsions, seizures*)
- tingling of the hands or feet, or sudden numbness or weakness in the legs or arms (*paraesthesia*)
- loss of feeling or touch (*hypoesthesia*)
- relapse of kidney disease causing large amounts of protein to appear in the urine
- visual disturbances or sensitivity to light (*visual disturbance, photophobia*)

These may be serious side effects. You or your child may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, (*anaphylactoid reactions, anaphylaxis, angioedema*)
- pinkish, itchy swellings on the skin, also called hives or nettle rash (*urticaria*)
- shortness of breath, wheezing or trouble breathing (*respiratory distress, respiratory failure, wheezing*)
- unusual stiffness causing loss of movement (*hypertonic episode*)

- a seizure or convulsion, which may be accompanied by a very high temperature (*febrile convulsions*)
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (*anaphylactic shock, syncope*)

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are rare.

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination (see "Before you are given Menjugate Syringe").

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you or your child feel unwell.

Do not be alarmed by this list of possible side effects.

You or your child may not experience any of them.

Storing Menjugate Syringe

Menjugate Syringe is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Menjugate Syringe:

- **Keep it where children cannot reach it.**
- **Keep Menjugate Syringe in the original pack until it is time for it to be given.**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze Menjugate Syringe.** Freezing destroys the vaccine.
- **Check the expiration date marked on the carton prior to use.**
- **Return vaccine to your doctor or pharmacist for proper**

disposal if the vaccine is expired or has been frozen

Product description

What it looks like

Menjugate Syringe is supplied as a vial and syringe. The vial contains the vaccine conjugate as a powder. The syringe contains the vaccine diluent. The contents of the vial and syringe are to be mixed prior to vaccination.

Ingredients

Active ingredients: Each 0.5 mL dose of the reconstituted vaccine (vaccine powder mixed with diluent) contains Meningococcal C oligosaccharide 10 micrograms, conjugated (chemically joined) to *Corynebacterium diphtheriae* CRM-197 protein 12.5 to 25.0 micrograms and aluminium hydroxide 1.0 mg as an adjuvant (a chemical added to increase immune response).

Other ingredients: mannitol, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, sodium chloride, water for Injections.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of Bovine Spongiform Encephalitis) has resulted from the administration of any vaccine product.

Menjugate Syringe does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer/Distributor/Supplier

Menjugate Syringe is manufactured by:
Novartis Vaccines and Diagnostics S.r.l., Italy

and sponsored by:

CSL Limited,
45 Poplar Road
Parkville 3052, Victoria
Australia

AUST R 93942

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