

NOVARTIS

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Comm. name/ country	Menjugate Full Liquid / IE
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Package leaflet: Information for the user

MENJUGATE®

10 micrograms suspension for injection

Meningococcal group C conjugate vaccine



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or of your child.
- If you or your child gets any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

- What is in this leaflet:**
1. What Menjugate is and what it is used for
 2. What you need to know before you or your child use Menjugate
 3. How to use Menjugate
 4. Possible side effects
 5. How to store Menjugate
 6. Content of the pack and other information

1. What Menjugate is and what it is used for

Menjugate is a vaccine that is used to prevent disease caused by a bacterium named *Neisseria meningitidis* group C (also referred to as meningococcal group C bacteria). The vaccine works by causing your body to make its own protection (antibodies) against these meningococcal group C bacteria.

Neisseria meningitidis group C bacteria can cause serious and sometimes life-threatening infections such as meningitis and septicaemia (blood poisoning).

This vaccine is used for active immunisation of children from 2 months of age, adolescents and adults and it can only protect against meningococcal group C bacteria. It cannot protect against other groups (strains) of meningococcal bacteria or against other causes of meningitis and septicaemia (blood poisoning). If at any time you or your child experiences neck pain, neck stiffness or a dislike of light (photophobia), drowsiness or confusion, red or purple bruise-like spots that do not fade under pressure you must contact your doctor or local Accident and Emergency Department immediately.

This vaccine cannot cause meningitis C (meningococcal group C disease).

This vaccine contains a protein (called CRM197) from the bacteria that cause diphtheria. **Menjugate does not protect against diphtheria.** This means that you (or your child) should receive other vaccines to protect against diphtheria when these are due or when advised by your doctor.

2. What you need to know before you or your child are given Menjugate

Do not use Menjugate if you or your child:

- ever had an **allergic reaction to the active** substances or any of the other ingredients of Menjugate (listed in section 6)
- ever had an **allergic reaction to diphtheria toxoid** (a substance used in a number of other vaccines)

Warnings and precautions

Fainting, feeling faint or other stress-related reactions can occur as a response to any needle injection. Tell your doctor or nurse if you have experienced this kind of reaction previously.

Talk to your doctor or nurse before you or your child are given Menjugate, if you or your child:

- have **haemophilia** or any other problem that may stop your blood from clotting properly (e.g. a too low amount of platelet called thrombocytopenia) or are taking any medicines that can influence blood clotting
- have a **weak immune system** for any reason (for example you (or your child) do not produce antibodies very efficiently, or you (or your child) are taking medicines that reduce your immunity to infections such as anti-cancer drugs or high doses of corticosteroids)

- had your **spleen removed** or have been told that your spleen does not work as it should
- have an **infectious illness or high fever**. In this case vaccination with Menjugate may have to be delayed. However, a minor infection (for example, a cold) is not a reason to delay vaccination.
- are **over 65 years** old
- suffer from a **kidney disease** in which large amounts of protein appear in the urine (called nephrotic syndrome). There have been reports of this condition reoccurring after vaccination.

This vaccine can only protect against meningococcal group C bacteria. It cannot protect against other types of meningococcal bacteria.

Latex-sensitive individuals – for syringe presentation: Although no natural rubber latex is detected in the syringe tip cap, the safe use of Menjugate in latex-sensitive individuals has not been established.

Other medicines and Menjugate

Tell your doctor or nurse if you (or your child) are using, have recently used or might use any other medicines.

Menjugate may be given at the same time as other vaccinations but any other injected vaccines must be given into a separate injection site, preferably in a different arm or leg from the site of the Menjugate injection. These include:

- Polio vaccines given by mouth or by injection
- Diphtheria and Tetanus vaccines alone or in combination with Whooping cough vaccine
- *Haemophilus influenzae* type B (Hib disease) vaccine
- Hepatitis B vaccine given alone or at the same time as combined vaccines against Diphtheria, Tetanus, Hib disease, Polio and Whooping cough.
- Measles, Mumps, and Rubella (MMR) combined vaccines
- Pneumococcal conjugate vaccine.

These other vaccines should be given at the recommended ages as normal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before Menjugate is given. Your doctor or

nurse may still advise you to have Menjugate if you are at high risk of infection with meningococcal group C bacteria.

Driving and using machines

You may feel dizzy or experience some other side effects after the injection. These could interfere with your driving or operating machinery. Do not drive or operate machinery until you know how Menjugate affects you.

Menjugate contains:

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium-free’.

3. How to use Menjugate

Menjugate will be given by your doctor or nurse.

The vaccine is usually given into the muscle of the thigh in infants, and into the shoulder muscle for older children, adolescents and adults. Your doctor or nurse will take care to ensure the vaccine is not given into a blood vessel and will make sure that it is injected into muscle and not into the skin.

For children 12 months and older, adolescents and adults: a single dose (0.5 ml) of the vaccine is recommended.

For infants 2 months up to 12 months of age: two doses of Menjugate should be given at least two months apart.

In order to maintain protection, a booster dose must be given after the infant course of two doses has been completed. Your doctor will advise you when your child should receive this.



For information on handling of the vaccine see the section for medical or healthcare professionals at the end of this leaflet.

If you use more Menjugate than you should

Since Menjugate will be given by either a doctor or nurse, and each injection is a single dose of 0.5 millilitres, it is very unlikely that you (or your child) will be given too much vaccine. If you have any concerns about the amount of vaccine you (or your child) have been given, speak to your doctor or nurse.

If you have any further questions on the use of Menjugate, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Menjugate can cause side effects, although not everybody gets them.

If a severe allergic reaction occurs (usually in less than 1 in 10,000 people) tell your doctor straight away or go immediately/ take your child to the nearest Accident and Emergency department because urgent medical help may be needed.

The **symptoms** of severe allergic reactions can include:

- Swelling of the lips, mouth, throat (which may cause difficulty in swallowing)
- Difficulty breathing with wheezing or coughing
- Rash and swelling of the hands, feet and ankles
- Loss of consciousness
- Very low blood pressure

These very rare reactions can occur immediately or very soon after the injection and there is usually a rapid recovery after the right treatment has been given.

Other allergic reactions may start some days after the vaccine is given.

These include:

- rashes, sometimes with itching, purple skin spots or blotches,
- blistering rashes that may also cause ulcers in the mouth and around the genital organs.

The most common side effects reported during clinical trials usually lasted only one to two days and were not usually severe. The side effects were:

Very common (may affect more than 1 in 10 people)

- In all age groups: redness, swelling and tenderness/pain at the injection site but these did not usually require further medical attention. Redness or swelling of at least

3 cm and tenderness causing discomfort with movement were rarely observed for more than 48 hours.

- Infants: being sick (vomiting)
- Infants and toddlers: irritability, drowsiness, difficulty sleeping, loss of appetite and diarrhoea.
- Secondary school children: headache
- Older children and adults: feeling generally unwell
- Adults: muscle and joint pains, feeling sick (nauseous)

Common (may affect up to 1 in 10 people)

- In all age groups: Fever (but rarely severe).
- Infants and toddlers: crying
- Toddlers: being sick (vomiting).
- Primary school children: headache

Other side effects reported during routine vaccination programmes include:

Very rare (may affect up to 1 in 10,000 people)

Different age groups:

- enlarged lymph glands
- dizziness
- faints
- numbness
- tingling sensation or pins and needles
- temporarily reduced muscle tone
- visual disturbances and sensitivity to light. These have usually occurred together with headache and dizziness.

Although fits have been reported very rarely after vaccination with Menjugate, it is thought that some of these reports in teenagers and adults may have been faints. In infants and young children, fits were usually associated with high fever. The majority of people affected have recovered rapidly.

There have been very rare reports of relapse of a kidney disorder called nephrotic syndrome following vaccination with this type of vaccine.

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.

Reporting of side effects

If you or your child gets any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Menjugate

Keep this vaccine out of the sight and reach of children.

Do not use Menjugate after the expiry date which is stated on the carton.

The vaccine consists of a vial or a syringe.

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the vial or the syringe in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your doctor or nurse how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Menjugate contains

Each 0.5 ml dose of the vaccine contains the following amount of **active** substance: 10 micrograms of *Neisseria meningitidis* group C (strain C11) oligosaccharide chemically joined to 12.5 to 25.0 micrograms of *Corynebacterium diphtheriae* CRM197 protein.

The active substance is adsorbed on aluminium hydroxide (0.3 to 0.4 mg Al³⁺) in 0.5 ml (1 dose) of vaccine.

The **other** ingredients are: sodium chloride, histidine, and water for injections (see also end of Section 2).

What Menjugate looks like and contents of the pack

Menjugate is a suspension for injection.

Each dose of Menjugate is supplied as a:

- Vial containing a white opalescent suspension or
- Syringe containing a white opalescent suspension

Pack sizes: 1, 5 or 10 doses. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Novartis Vaccines and Diagnostics S.r.l., Via Fiorentina 1, 53100 Siena, Italy

Manufacturer: Novartis Vaccines and Diagnostics S.r.l., Bellaria-Rosia, 53018 Sovicille (Siena), Italy

This leaflet was last revised in

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The following information is intended for healthcare professionals only:

Syringe:

Gently shake the syringe containing the vaccine before administration. Remove the syringe tip cap and fit a suitable needle. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. Ensure that no air bubbles are present in the syringe before injecting the vaccine. In the event of any foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine.

Vial:

Gently shake the vaccine vial. Using a syringe and a suitable needle (21G, 1 ½ inch (40 mm) length) withdraw the entire content of vial. Prior to injection, change the needle for one suitable for the administration. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. Ensure that no air bubbles are present in the syringe before injecting the vaccine. In the event of any foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine.