

Meningitec(R)

Meningococcal Serogroup C Conjugate Vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Meningitec. 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 Meningitec 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 Meningitec is used for

Meningitec is a vaccine used to help prevent meningococcal disease, an infection caused by the germ (bacteria) *Neisseria meningitidis* group C. The germ can cause meningitis, a serious brain infection that can cause death or brain damage and septicaemia, an infection of the blood. Meningococcal disease is rare. It mainly occurs in children under 4 years of age and teenagers, but anyone can get it, especially if they have come into contact with someone who has meningococcal disease.

Meningitec does not protect against all types of meningococcal disease or other germs that cause meningitis or septicaemia. It only works against

Neisseria meningitidis Group C bacteria. Meningitec does not work against meningococcal disease caused by *Neisseria meningitidis* Group A, B, W, Y.

How Meningitec works

Meningitec works by causing your body to produce its own protection against meningococcal disease. It does this by making substances called antibodies in the blood. These antibodies fight the germ *Neisseria meningitidis*. If a vaccinated person comes into contact with the germ, the body is usually ready to destroy it.

Your body usually takes several weeks after vaccination to develop protection against meningococcal disease. In Children less than 12 months of age, protection requires 4 doses of Meningitec. Children over 12 months of age, teenagers and adults, require only one dose. Most people will produce enough antibodies against meningococcal disease. However, as with all vaccines, 100% protection cannot be guaranteed.

It is not possible to get meningococcal disease from Meningitec, because it is not made from live or whole bacteria. However, you should remain alert for symptoms of possible coincidental meningococcal disease. The chance of a severe reaction from Meningitec is very small, but the risks from not being vaccinated against meningococcal disease may be very serious.

Before you are given Meningitec

When you or your child must not be given it

Do not have Meningitec if you have ever had an allergic reaction or severe neurological reaction to Meningitec, 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

Seizures (fits) are an example of a severe neurological reaction.

Do not have Meningitec if the expiry date (EXP) printed on the pack has been passed. If it has, use a new pack.

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

Before you or your child receive it

Tell your doctor if you or your child has any of the following medical conditions:

- * Blood disorders or bleeding disorders.

People with certain medical conditions such as blood or bleeding disorders and low platelet count should not have injections unless the benefits are greater than the risks. Discuss with your doctor the benefits

and risks of Meningitec.

If you or your child has any medical condition that affects the immune system, such as those listed below, you/your child's immune response may be lower than in those individuals with a healthy immune system. These conditions include:

- * HIV/AIDS
- * Cancer
- * Lowered immunity due to treatment with medicines such as steroids, cyclosporin or medicines used to treat cancer (including radiation).

You or your child's immune response may be lower than in those individuals with a healthy immune system.

Tell your doctor if you are pregnant or think you are pregnant.

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

Tell your doctor if you are breast-feeding.

It is not known whether Meningitec passes into breast milk.

Tell your doctor if your baby is under 6 weeks of age.

It is not known if Meningitec works in babies less than 6 weeks old.

Tell your doctor if your baby was born prematurely.

Vaccination of premature babies can cause apnoea (temporarily stopping breathing).

Tell your doctor if you or your child has 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 or your child plan to have other vaccines at the same time as Meningitec

Some vaccines are not routinely given at the same time as Meningitec.

Tell your doctor if you or your child has allergies to:

- * any other medicines, including other vaccines.
- * any other substances, such as foods, preservatives or dyes.

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

How Meningitec is given

Meningitec is given as an injection by a doctor or nurse, usually into the upper arm muscle. Babies may be given Meningitec into the upper thigh muscle. Meningitec should not be injected directly into the veins.

Meningitec can be given at the same time as DTP (Diphtheria, Tetanus and Whooping Cough), DTP-Hib (Diphtheria, Tetanus, Whooping Cough and Haemophilus influenzae type b), polio, MMR (Measles, Mumps, Rubella), Pneumococcal conjugate vaccine 7-valent and Hepatitis B vaccines. Each vaccine should be injected in a different part of the recipient's body.

How much is given?

Each dose is 0.5 mL.

When is Meningitec given?

Children under 12 months of age need a course of 4 injections in total. The first dose should be given at 2 months. Normally the second dose is given at 4 months and the third dose at 6 months. There should be at least one month between each injection. The fourth (booster) dose should be given after your child turns 12 months.

Children over 12 months of age, teenagers and adults require a single dose. It is not yet known if they may require an additional (booster) dose.

Your doctor or clinic nurse will tell you the correct vaccination schedule if your child is already older than 2 months.

If your child misses a dose

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

After having Meningitec

Things you must do

Keep an updated record of the vaccinations.

Keep follow-up appointments with your doctor or clinic.

It is important that your child has follow-up doses of Meningitec at the appropriate times to make sure the vaccine has the best chance of providing protection against Neisseria meningitidis Group C.

You or your child should have any blood tests when your doctor says to.

Your doctor may wish to test your, or your child's, response to Meningitec to make sure that you have developed protection against meningococcal disease.

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

Dizziness and sleepiness can sometimes happen in people who have received Meningitec.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child does not feel well after having Meningitec.

Meningitec 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 may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Mild Effects

The following is a list of the more common side effects. These side effects are usually mild and usually last for only a few hours. They should not require treatment.

Tell your doctor or pharmacist if you notice any of the following side effects and they worry you or are ongoing after vaccination:

- * local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars
- * headache
- * aching muscles
- * dizziness and light-headedness
- * sleepiness or unsettled sleep
- * generally feeling unwell or irritability
- * unusual high-pitched crying
- * eating and drinking less than usual, loss of appetite
- * diarrhoea or vomiting
- * stomach cramps or pain
- * heartburn
- * fever

A single dose of paracetamol may be needed to reduce fever. If your baby has any of these side effects after one vaccination, they may have the same reaction after the next Meningitec injection.

Other very rare side effects include:

- * swollen glands in the neck, armpits or groin
- * pins and needles
- * loss of muscle tone
- * decreased sensitivity to touch.

Serious Effects

If any of the following happen, tell your doctor or pharmacist 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
- * red or purple flat pinhead spots or bruising appear under the skin
- * shortness of breath, wheezing or trouble breathing, chest pain
- * temporarily stopping breathing
- * a seizure (fit) or convulsion, which may be accompanied by a very high temperature
- * feeling weak or paralysed, or generally feeling sore or tender
- * dark coloured urine or pale stools
- * collapse, or shock-like state
- * relapse of a kidney condition called nephrotic syndrome.

These are very serious side effects that may need urgent medical attention.

If you or your child has any other unexpected reaction following vaccination, please contact your doctor.

Other side effects not listed above may occur.

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

You may not experience any of them.

Storing Meningitec

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

- * Keep it where children cannot reach it.
- * Keep Meningitec in the original pack until it is time for it to be given.
- * Keep it in the refrigerator, between 2 degrees C and 8 degrees C. Do not freeze Meningitec. Freezing destroys the vaccine.

Product description

What it looks like

Meningitec is supplied in glass pre-filled syringes. The single dose syringes contain 0.5 mL. The vaccine is a white suspension.

Ingredients

Active ingredients:

Each syringe contains 10 micrograms meningococcal Group C oligosaccharide conjugated to 15 micrograms of diphtheria CRM197 protein.

Other ingredients:

- * Aluminium phosphate
- * Sodium chloride
- * Water for injections

Meningitec does not contain thiomersal, phenol, lactose, sucrose, gluten, tartrazine or any other azo dyes.

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 encephalopathy) has resulted from the administration of any vaccine product.

Supplier

Wyeth Australia Pty. Limited

17-19 Solent Circuit, Norwest
Business Park,
Baulkham Hills, NSW 2153.
ABN 16 000 296 211

For further information please
contact Wyeth on 1 800 500 498
(toll-free in Australia) 0800 447 400
(toll-free in New Zealand) or E-mail:
medinfo@wyeth.com.

Australian Registration Number: Pre-
filled syringe - AUST R 134363

New Zealand

Distributed in New Zealand by:
Pharmacy Retailing (NZ) Limited
58 Richard Pearce Drive, Airport
Oaks, Auckland

Date of Preparation:

This leaflet was prepared on 15 June
2009.

(R) Registered Trade Mark