PACKAGE LEAFLET: INFORMATION FOR THE USER

Meningitec suspension for injection in pre-filled syringe
Meningococcal serogroup C oligosaccharide conjugate vaccine (adsorbed)

Read all of this leaflet carefully before you/your child receives this vaccine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you/your child. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Medicinal product subject to medical prescription.

What is in this leaflet:

What Meningitec is and what it is used for
Meningitec is a meningococcal serogroup C vaccine.

Meningitec helps protect you/your child against diseases such as: meningitis and septicaemia (blood poisoning).

Meningitec is a vaccine that is used in children from 2 months of age, adolescents and adults to help prevent infections caused by bacteria called *Neisseria meningitidis* serogroup C. It will not protect against other serogroups of *Neisseria meningitidis* or other bacteria or viruses that sometimes cause meningitis and septicaemia (blood poisoning). The vaccine works by causing your body to produce its own protection (antibodies) against this bacteria. *Neisseria meningitidis* serogroup C bacteria can cause serious and sometimes life-threatening infections such as meningitis and septicaemia (blood poisoning). This vaccine contains no live organism and it cannot cause meningitis C (meningococcal C disease).

Remember that no vaccine can provide complete and life-long protection in all people vaccinated.

2. What you need to know before you/your child receive Meningitec

Meningitec should not be given:
- if you/your child are allergic (hypersensitive) to the active substances or any of the other ingredients of Meningitec (listed in Section 6).
- if you/your child have shown signs of an allergic reaction to any other vaccine that contains diphtheria toxoid or the diphtheria CRM_{197} protein.
- if you/your child have shown signs of an allergic reaction to a previous dose of Meningitec.
- if you/your child have an illness with a high temperature, vaccination is usually postponed but it can go ahead if the fever and illness are only mild, but talk to your doctor or nurse first.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before vaccination:
- if you/your child have haemophilia or any other problem that may stop your blood from clotting properly, or if you/your child are taking any medicines that stop your blood from clotting properly. If so, your doctor may choose to take special precautions.
- if you/your child have a weak immune system, or if you/your child have recently had or are currently having a course of treatment with radiation, corticosteroids or any other medicines that can lower your immunity to infections. Meningitec can still be given but it may not protect as well as in other people.
- if you/your child suffer from a 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/your child can still have Meningitec depending on the exact type of kidney problem you have.

Although Meningitec contains a protein (called CRM_{197}) from the bacteria that cause diphtheria, it does not protect against diphtheria disease, so it is important that you/your child receives other vaccines that protect against diphtheria when these are due. Your doctor or nurse can advise you.

Meningitec has been given mainly to infants from the age of 2 months, children and young adults. No information is yet available about giving Meningitec to people aged 65 years and over or infants under the age of 2 months.

Other medicines/vaccines and Meningitec
Tell your doctor or pharmacist if you/your child are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription or have recently received any other vaccines.
Unless told otherwise by your doctor or nurse, you/your child should continue to take prescribed medicines as usual before and after vaccination.

Meningitec can be given at the same time as other vaccines against one or more of the following diseases:
Polio (including vaccines against polio that are given by mouth or by injections)
Diphtheria
Tetanus
Whooping cough (pertussis)
Haemophilus influenzae type b (known as Hib vaccines)
Hepatitis B
Measles, mumps and rubella (German measles)
Pneumococcal disease (pneumococcal conjugate vaccine 7-valent and pneumococcal conjugate vaccine 13-valent)

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before vaccination.

Meningitec would not usually be given to pregnant or breast feeding woman unless it is thought very necessary by your doctor that the pregnant or breast feeding women should be vaccinated as soon as possible.

Driving and using machines

After receiving Meningitec, sleepiness, dizziness and other side effects may occur that could interfere with driving or operating machinery (see possible side effects).

Do not drive or operate machinery until you know how Meningitec affects you.

Meningitec contains sodium chloride
One of the ingredients of Meningitec is sodium chloride. This vaccine contains less than 1 mmol of sodium (23 mg) per 0.5 ml dose and is therefore essentially 'sodium free'.

3. How Meningitec is given

Meningitec will be given to you/your child by a doctor or nurse.

Your doctor or nurse will make sure that the vaccine is injected correctly into a muscle (not into or near nerves or blood vessels or too shallow under the skin) and that Meningitec is not mixed with other vaccines in the same syringe. The vaccine is a 0.5 ml injection and it is usually given into the muscle of the thigh in infants and into the shoulder muscle for older children, adolescents and adults. It should not be given into the buttock area.

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

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

For adults, adolescents and children over the age of 12 months who have not previously been immunised with Meningitec, a single dose (0.5 ml) of the vaccine is recommended.

Meningitec will be given as a separate injection into a different body site when it is given at the same time as another injected vaccine.

If you are given more Meningitec than you should have been given

Overdose is very unlikely because the vaccine is provided in single-dose pre-filled syringes and is given by a doctor or nurse.

There have been a few reports of too many doses being given, too much vaccine being given, or doses being given too close together. In most cases, there were no side effects while sometimes there were side effects that were similar to those seen after routine and correct use of Meningitec.

If you forget to go to the doctor

If you forget to go to the doctor or nurse at the scheduled time, ask your doctor or nurse for advice.

4. Possible side effects

Like all vaccines, Meningitec can cause side effects, although not everybody gets them.

Serious allergic reactions are always a very rare possibility after receiving a vaccine. These reactions may include:

- swollen face, tongue or pharynx,
- difficulty to swallow,
- skin swelling (hives) and difficulties to breathe,
- low blood pressure causing collapse and shock.

When these signs or symptoms occur they usually develop very quickly after the injection is given and while the person affected is still in the clinic or doctor's surgery. If any of these symptoms occur after leaving the place where your injection was given, you must consult a doctor IMMEDIATELY.

Very rarely, severe skin rashes can occur that can cover much of the body and lead to blistering and peeling. The inside of the mouth and the eyes can also be affected. Other less serious allergic reactions include rashes that may be red and lumpy, itching, and a later general illness that can cause symptoms such as fever and swelling of the joints.

This vaccine cannot cause meningitis C (meningococcal C disease). If you or your child experiences neck pain, neck stiffness or a dislike of light (photophobia), drowsiness or confusion, or red or purple bruise-like spots that do not fade under pressure you should contact your doctor or local Accident and Emergency Department immediately to rule out other causes.

If you have previously been told by your doctor that you/your child suffer from nephrotic syndrome (a kidney disease which may result in swelling, particularly around the face or eyes, protein in the urine making it appear frothy and/or weight gain) there may be an increased chance that this condition will reoccur within a few months after vaccination. You should tell your doctor if you notice similar symptoms after vaccination.

The frequencies of side effects that are described in this section are:
Very common = occurred in more than one in ten people who received the vaccine.
Common = occurred in between one in ten and one in a hundred people who received the vaccine.
Very Rare = occurred in less than one in ten thousand people who received the vaccine.

Very Common side effects include:
In all age groups - swelling and tenderness or pain at the injection site.
In infants and toddlers - loss of appetite, irritability, sleepiness or disturbances of sleeping patterns, being sick, diarrhoea.
In adults – headaches.
In pre-school children – fever.

Common side effects include:
In all age groups - fever (very common in pre-school children), but this is rarely severe.
In infants and toddlers – crying.
In children between 3-6 years – sleepiness, headache, irritability.
In adults – muscle pains, sleepiness.

Very rare side effects include (in all age groups unless already mentioned above):
Swelling of the glands, dizziness, faints, numbness, tingling sensation or pins and needles, feeling or being sick, bruising or bleeding into the skin, relapses of certain kidney disorders in which large amounts of protein appear in the urine.

Very rarely a reduction in muscle tone has been observed (floppiness), sometimes with reduced alertness or responsiveness of the infant and a pale or bluish appearance to the skin.

Fits (seizures) have been reported very rarely after vaccination with Meningitec including some fits in people who already had fits at times. In teenagers and adults, some of the reports of fits may actually have been fainting attacks. In infants and young children seizures were usually associated with fever and were likely to be febrile convulsions. Most people recovered rapidly after the fit.

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 get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.
Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5. How to store Meningitec

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

Do not use Meningitec after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (+2°C to +8°C). Do not freeze. Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Meningitec contains

The active substance in each 0.5 ml dose is:
10 micrograms Meningoccocal serogroup C oligosaccharide*

*conjugated to the CRM_{197} carrier protein and adsorbed on aluminium phosphate (0.125 mg)

The other ingredients are sodium chloride and water for injections.

What Meningitec looks like and contents of the pack

Meningitec is a suspension for injection supplied in pre-filled syringes of 0.5 ml in pack sizes of 1 and 10 (with or without needle) and in a multipack of 2 packs of 10 pre-filled syringes (without needle). **After shaking, the vaccine is a homogeneous, white suspension.** Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

- Marketing Authorisation Holder
  Nuron Biotech B.V.
  Strawinskylaan 1143, Toren 11-C
  1077XX Amsterdam, NL

- Manufacturer responsible for batch release
  Wyeth Pharmaceuticals
  New Lane
  Havant P09 2NG
  United Kingdom

This leaflet was last revised in September 2013

Detailed information on this medicine is available on the web site of the Irish Pharmaceutical Healthcare Association Medicines Compendium (www.medicines.ie).

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