

Package leaflet: Information for the user

Menitorix powder and solvent for solution for injection

Haemophilus type b and *Meningococcal* group C conjugate vaccine

Read all of this leaflet carefully before your child starts receiving this vaccine 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, pharmacist or nurse.
- This vaccine has been prescribed for your child only. 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.

What is in this leaflet:

1. What Menitorix is and what it is used for
2. What you need to know before your child receives Menitorix
3. How Menitorix is given
4. Possible side effects
5. How to store Menitorix
6. Contents of the pack and other information

1. What Menitorix is and what it is used for

Menitorix is a vaccine that can be given to children after the age of 2 months up to 2 years to prevent infectious diseases caused by *Haemophilus influenzae* type b (Hib) and *Neisseria meningitidis* group C (MenC) bacteria. The vaccine works by causing the body to produce its own protection (antibodies) against these bacteria. The vaccine cannot cause Hib and MenC.

- ***Haemophilus influenzae* type b (Hib):** Hib bacteria most frequently cause meningitis (inflammation of the coverings of the brain and spinal cord). Even after recovery from Hib meningitis there can be complications such as mental retardation, spastic paralysis, deafness or epilepsy. Hib infection can also cause a life-threatening inflammation of the throat with severe swelling that can cause suffocation. Less commonly, the bacteria can infect other parts of the body, particularly the lungs (causing pneumonia) and the bones and joints.
- ***Neisseria meningitidis* group C (MenC):** Like Hib bacteria, MenC bacteria most frequently cause meningitis. They may also cause severe blood infections and spread throughout the body.

Vaccination is the best way to protect against diseases caused by these bacteria. Remember, however, that no vaccine can provide complete, life-long protection in all people vaccinated. Also, Menitorix can only protect against meningitis and other infections caused by *Haemophilus influenzae* type b (Hib) and *Neisseria meningitidis* group C (MenC). It cannot protect against meningitis caused by other bacteria or viruses, including other types and groups of *Haemophilus* or *Neisseria* bacteria.

2. What you need to know before your child receives Menitorix

Menitorix should not be given:

- if your child has previously had any allergic reaction to Menitorix, to any Hib or MenC vaccine, to tetanus toxoid or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

- if your child has a high temperature (38°C or above) or a severe infection. It is usual to wait until the child is better before giving the vaccine. A minor infection such as a cold should not be a problem but talk to your doctor or nurse first.

Remember that the first dose of Menitorix should not be given before your child is 2 months of age.

Warnings and precautions

Talk to your doctor or nurse before your child receives Menitorix

- if your child has a bleeding problem or bruises easily.
- if your child takes medicines or has any treatment which may affect the immune system. Also, if your child has HIV infection or any other illness that can reduce his or her immunity to infections. Your child can still be given Menitorix if your doctor or nurse advises it but your child may not develop as good protection against Hib and MenC infections as other children.
- if your child receives treatment that blocks the part of the immune system known as complement activation, such as eculizumab. Even if your child has been vaccinated with Menitorix your child remains at increased risk of disease caused by the MenC bacteria.
- if your child was born prematurely (before 37 weeks). Menitorix can be given from the age of 2 months after birth onwards but it is not known if protection against Hib and MenC will be as good as in children born at term.

In the first 1-2 weeks after a dose of Menitorix it is possible that urine tests to detect Hib infection could give the wrong (false positive) results.

Other medicines and Menitorix

Tell your doctor or nurse if your child is taking, has recently taken or might take any other medicines.

Menitorix can be given at the same time as vaccines intended to protect against one or more of diphtheria, tetanus, whooping cough, polio, hepatitis B, pneumococcal conjugate vaccine and combined vaccines against measles, mumps and rubella (MMR). Any other vaccines that are given at the same time as Menitorix will be injected separately at different parts of the body.

Although Menitorix contains tetanus toxoid (inactivated bacterial toxin), which is used to immunise people against tetanus (lockjaw), it is still necessary that your child should receive the recommended childhood vaccinations against tetanus.

Menitorix contains sodium

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

3. How Menitorix is given

Each dose of Menitorix is a single injection of half a millilitre (0.5 ml). The nurse or doctor will give Menitorix as an injection into the muscle (usually into the thigh muscle but in toddlers the arm muscle can be used) and will make sure that the vaccine is not given into a blood vessel or into the upper layer of the skin.

If Menitorix is used in infants for the first vaccinations against Hib and MenC:

Your child will receive three doses of Menitorix. The first injection can be given from the age of 2 months onwards and there should be a gap of at least four weeks between injections.

Alternatively, from the age of 3 months, your child may receive 2 injections, each separated by 2 months.

If your child was born prematurely, he/she will receive 3 injections from 2 months to 12 months of age with an interval of at least 2 months between each one.

If Menitorix is used to boost protection against Hib and MenC:

After the first course of vaccinations against Hib and MenC has been completed a booster dose of Hib and MenC should be given, usually at some time in the second year of life.

Menitorix can be used to boost protection in children who received Menitorix previously or in children who previously received other vaccines against these diseases (including children who received two doses of a MenC vaccine in early life).

If your child receives more Menitorix than he/she should

It is very unlikely that your child will receive too much or too little vaccine because each dose is provided in a separate vial and the vaccine is given by a doctor or nurse. If you are concerned about the dose or doses that have been given, please talk to your doctor or nurse.

If you forget to take your child for vaccination with Menitorix

Your doctor or nurse will advise when your child should attend for these injections. If you miss an appointment, it is very important that you contact the surgery or clinic and make a new appointment for your child to have the missed dose or doses as soon as possible.

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

4. Possible side effects

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

Severe allergic reactions can occur to any vaccine but they are very rare and are usually seen in less than 1 in 10,000 people who are vaccinated. Your child may be asked to stay in the surgery or vaccination area for a short time after vaccination to check that he or she does not have an immediate allergic reaction. Tell the doctor or nurse immediately if your child develops a rash (which may be raised or lumpy), tightness of the throat, swelling of the face or neck or shortness of breath. Other possible symptoms of a severe allergic reaction include a drop in blood pressure and unconsciousness. It is very important that your child has immediate medical treatment for any severe allergic reaction. If the symptoms start after you have left the clinic, you should get medical help as soon as possible (for example, go to the nearest accident and emergency department).

In clinical trials that involved giving Menitorix for the first vaccinations against Hib and MenC or to boost protection against these diseases the side effects that occurred after vaccination were:

- ◆ **Very common (these may occur with more than 1 in 10 doses of the vaccine)**
 - Pain, redness or swelling at the site of the injection
 - Fever (temperature of 38°C or above)
 - Irritability
 - Loss of appetite
 - Sleepiness

- ◆ **Common (these may occur with up to 1 in 10 doses of the vaccine)**
 - Injection site reaction, such as hard lump

- ◆ **Uncommon (these may occur with up to 1 in 100 doses of the vaccine)**
 - Crying
 - Diarrhoea
 - Being sick
 - Skin allergies
 - Fever more than 39.5°C
 - Rash

- ◆ **Rare (these may occur with up to 1 in 1,000 doses of the vaccine)**
 - Abdominal pain
 - Sleeplessness
 - Generally feeling unwell

Other side effects have occurred in the days or weeks after vaccination with Menitorix. The frequency cannot be estimated from the available data. They include:

Allergic reactions (these can be recognised by itchy rash of the hands and feet, swelling of the eyes and face, difficulty in breathing or swallowing), swelling of the glands, dizziness, convulsions (fits) with high temperature, unusual muscle slackness, headache.

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.

Some other side effects have been reported very rarely (in less than 1 per 10,000 doses of vaccine) in children who have received other MenC containing vaccines. They include: collapse or shock, the child not responding to his or her parents for a time after vaccination, fainting, convulsions in children who have had them before, lack of sensation or an increased sensation (for example pain, pins and needles or itching at the injection site), joint pain, or purple spots or patches under the skin.

This vaccine cannot cause MenC or Hib infections. If 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 your child suffers 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 in your child after vaccination.

Reporting of side effects

If your child gets 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 via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Menitorix

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

Do not use this vaccine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Do not freeze.

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

After reconstitution, the vaccine should be administered promptly or kept in the refrigerator (2°C – 8°C). If it is not used within 24 hours, do not administer the vaccine.

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

6. Contents of the pack and other information

What Menitorix contains

- The active substances are:
 - Haemophilus* type b polysaccharide (polyribosylribitol phosphate) 5 micrograms
 - conjugated to tetanus toxoid as carrier protein 12.5 micrograms
 - Neisseria meningitidis* group C (strain C11) polysaccharide 5 micrograms
 - conjugated to tetanus toxoid as carrier protein 5 micrograms
- The other ingredients are:
 - Powder: trometamol, sucrose
 - Solvent: sodium chloride, water for injections.

What Menitorix looks like and contents of the pack

Menitorix is supplied as a white powder of Hib-MenC vaccine in a glass vial, together with half a millilitre (0.5 ml) of clear colourless sodium chloride solvent in a pre-filled syringe for a 1 dose vaccine. This powder is dissolved in the solvent provided, just before injection.

Menitorix is available in packs of 1 or 10 with 2 or 20 separate needles or without needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Ltd.
12 Riverwalk
Citywest Business Campus
Dublin 24

Manufacturer

GlaxoSmithKline Biologicals s.a.
Rue de l'Institut 89
B-1330 Rixensart
Belgium

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium, Ireland, United Kingdom (Northern Ireland) Menitorix

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Other sources of information

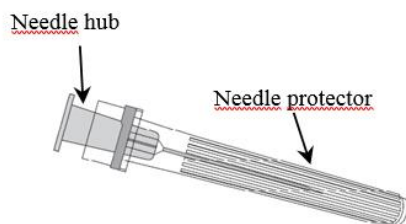
Detailed information on this medicine is available on the website of the Health Products Regulatory Authority.

The following information is intended for healthcare professionals only:

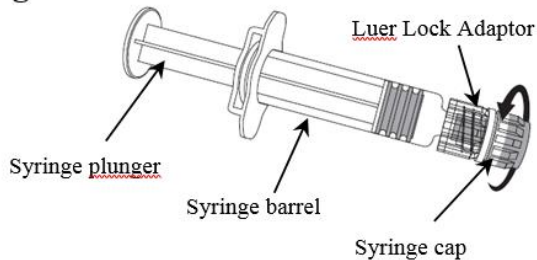
Menitorix must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder.

To attach the needle to the syringe, carefully read the instructions given with pictures 1 and 2. However, the syringe provided with Menitorix might be slightly different (without screw thread) than the syringe illustrated. In that case, the needle should be attached without screwing.

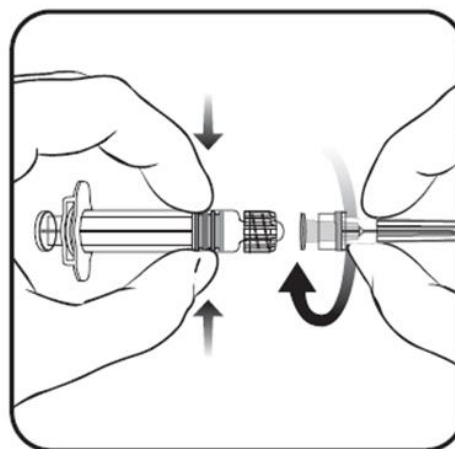
Needle



Syringe



Picture 1



Picture 2

Always hold the syringe by the barrel, not by the syringe plunger or the Luer Lock Adaptor (LLA), and maintain the needle in the axis of the syringe (as illustrated in picture 2). Failure to do this may cause the LLA to become distorted and leak.

During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.

1. Unscrew the syringe cap by twisting it anticlockwise (as illustrated in picture 1). Whether the LLA is rotating or not, please follow below steps:
2. Attach the needle to the syringe by gently connecting the needle hub into the LLA and rotate a quarter turn clockwise until you feel it lock (as illustrated in picture 2).
3. Remove the needle protector, which may be stiff.
4. Add 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 and 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, do not administer the vaccine.

5. Withdraw the entire contents of the vial.

6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach the injection needle by repeating step 2.

After reconstitution, the vaccine should be administered promptly or kept in the refrigerator (2°C – 8°C). If it is not used within 24 hours, do not administer the vaccine.

Experimental data show that the reconstituted vaccine could also be kept for up to 24 hours at ambient temperature (25°C). If it is not used within 24 hours, do not administer the vaccine.

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

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