

MENITORIX®

Haemophilus influenzae type b Polyribose ribitol phosphate and group C Meningococcal polysaccharide conjugate vaccine

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use MENITORIX.

This leaflet answers some common questions about MENITORIX. It does not contain all of the available information.

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

All medicines have risks and benefits. Your doctor has weighed the expected benefits of your child having MENITORIX against the possible risks.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is MENITORIX used for?

MENITORIX is a vaccine that can be given to children to prevent illness 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 these serious diseases.

- **Haemophilus influenzae type b (Hib):** Hib bacteria most often cause meningitis (inflammation of the coverings of the brain and spinal cord). Even after recovery from Hib meningitis there can be problems from the illness such as mental retardation, spastic paralysis, deafness or epilepsy. Hib infection can also cause severe swelling of the throat that can cause severe breathing problems (suffocation). Less commonly, the bacteria can infect other parts of the body, such as the lungs and the bones and joints.
- **Neisseria meningitidis group C (MenC):** Like Hib bacteria, MenC bacteria most often cause meningitis. They may also cause severe blood infections and infect the heart, throat and other organs. Death from MenC infections may be very rapid.

As with all vaccines, MENITORIX may not protect all people who are vaccinated.

Also, MENITORIX does not protect against meningitis caused by other bacteria or viruses, including other types and groups of *Haemophilus* or *Neisseria* bacteria.

Before your child receives MENITORIX

MENITORIX should not be given if your child:

- has had any allergic reaction to Menitorix, to any Hib, MenC or tetanus vaccine, or any ingredient in this vaccine. The active substances and other ingredients in Menitorix are listed at the end of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Before your child is vaccinated, make sure your doctor knows if any of the following apply to your child:

- has a severe infection with a high temperature. In these cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- has a bleeding problem or bruises easily
- is taking medicines or having 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 immunity as other children
- has breathing difficulties, please contact your doctor. This may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy).

Fainting can occur following, or even before, any needle injection, therefore please tell the doctor or nurse if your child fainted with a previous injection.

Using other medicines or vaccines

Please tell your doctor if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription or has recently received any other vaccine.

MENITORIX may be given at the same time your child receives other normally recommended vaccinations, such as diphtheria (D), tetanus (T), pertussis (whooping cough) (Pa), inactivated polio (IPV), hepatitis B (HBV), combined measles-mumps-rubella (MMR) and pneumococcal vaccines.

MENITORIX must not be used if:

- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering

Tell your doctor if your child is:

- taking any other medicines, including medicines you buy without a prescription.

How MENITORIX is given

If your child has received three doses of a Haemophilus influenzae type b vaccine during the first year of life, he/she may receive a dose of MENITORIX in the second year of life.

In order to get the most benefit from the vaccine, make sure your child finishes the complete vaccination course as recommended by your doctor.

Menitorix is given as an injection into the muscle.

If a dose is missed

If your child misses a scheduled dose, talk to your doctor and arrange another visit.

It is important that you follow the instructions of your doctor or nurse regarding return visits. If you forget to go back to your doctor at the scheduled time, ask your doctor for advice.

What are the side effects?

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

Tell your doctor or nurse as soon as possible if your child does not feel well during or after having had a dose of MENITORIX.

Side effects found to occur with MENITORIX include:

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 (more than or equal to 38°C)
- Drowsiness
- Loss of appetite
- Irritability

Common (these may occur with up to 1 in 10 doses of the vaccine):

- Injection site reaction, such as a hard lump

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- Crying
- Diarrhoea
- Vomiting
- Skin allergies
- Generally feeling unwell
- High 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
- Fatigue

Very rare (these may occur with up to 1 in 10,000 doses of vaccine)

Contact your doctor immediately or take your child to the casualty department of your nearest hospital if any of the following happens:

- Convulsions (fits) caused by a fever.
- Sudden life-threatening allergic reaction. Symptoms include 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,
 - shortness of breath, wheezing or trouble breathing.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor or pharmacist if you notice any side effects which are not mentioned here.

Do not be alarmed by this list of possible side-effects. Your child may not experience any of them.

How do I store MENITORIX?

MENITORIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store MENITORIX always:

- Keep MENITORIX in a refrigerator stored between +2°C and +8°C. **DO NOT FREEZE.** Do not store it in the bathroom, or leave it in the car. Avoid exposing the vaccine to sunlight.
- Keep the vaccine out of reach and sight of children.
- Keep MENITORIX in the original pack in order to protect from light.

Ask your pharmacist what to do with any left over MENITORIX that has expired or has not been used.

Product description

What MENITORIX looks like

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. The powder is dissolved in the solvent provided, just before injection.

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

Ingredients

MENITORIX contains agents that stimulate an immune response to *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroup C bacteria.

MENITORIX also contains trometamol, sucrose.

The diluent contains the excipients sodium chloride and water for injections.

Sponsor

MENITORIX is supplied in

Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4,
436 Johnston Street,
Abbotsford, Victoria, 3067

MENITORIX is supplied in New

Zealand by:

GlaxoSmithKline NZ Limited
AMP Centre
Cnr Albert & Customs Streets
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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The information provided applies only to: MENITORIX®.

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