Patient Information Leaflet

MENACTRA

Meningococcal Polysaccharide vaccine, Groups A, C, Y and W-135 combined

Approved 29 July 2014

South Africa

APPROVED PATIENT INFORMATION LEAFLET FOR MENACTRA®

Read this patient information leaflet carefully before vaccination.

Keep this patient information leaflet. You may need to read it again.

If you need more information or advice, ask your doctor or pharmacist.

You must contact a doctor if your symptoms worsen or do not improve.

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

MENACTRA®, Solution for Injection

Descriptive name:

MENACTRA®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

WHAT MENACTRA VACCINE CONTAINS:

Active substances:

Each dose of MENACTRA vaccine (0,5 ml) contains the following components:

- Meningococcal (Serogroup A) Polysaccharide (Monovalent Conjugate) 4,0 mcg
- Meningococcal (Serogroup C) Polysaccharide (Monovalent Conjugate) 4,0 mcg
- Meningococcal (Serogroup Y) Polysaccharide (Monovalent Conjugate) 4,0 mcg
- Meningococcal (Serogroup W-135) Polysaccharide (Monovalent Conjugate) 4,0 mcg

Diphtheria toxoid protein approximately 48 mcg

*Diphtheria toxoid quantity is approximate and dependent on the conjugate polysaccharide to protein ratio.

The other ingredients are:

- Sodium chloride (4,35 mg), Sodium phosphate dibasic anhydrous (0,348 mg),Sodium phosphate monobasic (0,352 mg)

WHAT MENACTRA VACCINE IS AND WHAT IT IS USED FOR:

MENACTRA is a vaccine. Vaccines are used to protect against infectious diseases.

MENACTRA vaccine is given to protect persons from 9 months through 55 years of age against meningococcal disease. It allows the body to produce enough antibodies to provide a defense against the bacteria that cause meningococcal disease.

BEFORE YOU USE MENACTRA VACCINE:

You should not be given Menactra vaccine:

- If you are allergic (hypersensitive) to the active substance or any of the other ingredients of MENACTRA vaccine listed.
- If you have an illness with febrile or acute infection, the vaccination shall be postponed until after you have recovered.
- If you have been previously diagnosed with Guillain-Barré syndrome.
- If you are younger than 9 months of age or older than 55 years of age.

***Take special care with MENACTRA* vaccine:**

- Tell your doctor if you have been previously diagnosed with Guillain-Barré syndrome or any brain disorder.
- Tell your doctor if you are pregnant or breastfeeding.

Your doctor should make sure the benefits of vaccination outweigh the risks when recommending MENACTRA vaccine.

Taking other medicines

Medicines that may reduce your immune response, such as corticosteroids (for example prednisone), medicines used to treat cancer (chemotherapy), radiotherapy or other medicines affecting the immune system. **Tell your doctor if you have been treated with such medicines.** Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Having other vaccines

Your doctor will advise you if MENACTRA vaccine is to be given with another vaccine. MENACTRA vaccine may be given at the same time as:Typhoid vaccine, and Td (tetanus and diphtheria), Pneumococcal 7-valent conjugate vaccine (PCV), measles, mumps and rubella vaccine (MMR), varicella virus vaccine (V), measles, mumps rubella and varicella vaccine (MMRV), Hepatitis A vaccine (Hep A), *Haemophilus influenza* type B (Hib), bivalent or quadrivalent Human Papillomavirus (HPV).

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

PREGNANCY AND BREASTFEEDING:

Pregnancy

Animal reproduction studies have not demonstrated a risk with respect to effects on pregnancy and embryo-fetal development, parturition and postnatal development. No studies have been performed in pregnant women and spontaneously reported post-marketing data on the use of this vaccine in pregnant women are limited. MENACTRA vaccine should be given to a pregnant

woman only if clearly needed, such as during an outbreak or prior to necessary travel to an endemic area, and only following an assessment of the risks and benefit.

Considering the severity of the meningococcal disease, pregnancy should not preclude vaccination when risk is clearly identified.

Lactation

It is not known whether the active substances included in the vaccine are excreted in human milk, but antibodies to the polysaccharides have been found to be transferred to the suckling offspring of mice.

Animal studies conducted in mice have not shown any harmful effect on the postnatal development of offspring exposed through breastfeeding to MENACTRA vaccine -induced maternal antibodies.

The effect on breastfed infants of the administration of MENACTRA vaccine to their mothers has not been studied. The risks and benefits of vaccination should be assessed before making the decision to immunise a breastfeeding woman.

DRIVING AND USING MACHINES:

No studies on the effects on the ability to drive and use machines have been performed.

The vaccine is unlikely to affect your ability to drive or use machines.

HOW TO USE MENACTRA VACCINE:

MENACTRA vaccine is administered to you by your doctor or your nurse.

A dose of MENACTRA vaccine (0,5 ml) is injected into the muscle.

In children 9 through 23 months of age, MENACTRA vaccine is given as a 2-dose series at least three months apart. Individuals 2 through 55 years of age receive a single dose.

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

Do not share the vaccine prescribed for you with others.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

POSSIBLE SIDE EFFECTS:

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medication, please consult your doctor, pharmacist or other health care professional for advice.

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

The most common local side effects with MENACTRA vaccine include:

- pain, tenderness, redness, hardness and swelling at the injection site

Systemic side effects include:

- headache, tiredness (fatigue), feeling unwell (malaise)
- joint pain (arthralgia)
- fever, chills
- loss of appetite, diarrhoea, vomiting
- rash
- irritability, drowsiness (in children)

These side effects usually clear up within a few days. If events continue or become severe, please tell your doctor or pharmacist.

Other side effects that have been reported very rarely include:

- Hypersensitivity reactions such as wheezing, difficulty breathing, upper airway swelling low blood pressure (hypotension), skin reactions for which symptoms may include itchiness of the skin (urticarial, pruritis) and redness of the skin (erythema)
- Sudden severe allergic reaction (anaphylactoid/anaphylactic reactions), for which symptoms may include 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
- neurological disorders that may result in confusion, numbness or tingling, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (Guillain-Barré syndrome, acute disseminated encephalomyelitis, transverse myelitis)
- dizziness
- fainting
- convulsion
- drooping eyelid and sagging muscles on one side of the face (facial palsy)
- tingling or numbness of the hands or feet (paraesthesia)
- sore, aching muscles (myalgia)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

HOW TO STORE MENACTRA VACCINE:

Store between +2 °C to +8 °C (i.e.in a refrigerator). DO NOT FREEZE.

Discard product if it has been exposed to freezing.

STORE IN OUTER CARTON UNTIL BEFORE USE. PROTECT FROM LIGHT.

KEEP OUT OF REACH OF CHILDREN.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRESENTATION OF MENACTRA VACCINE:

The vaccine is available in a 0,5 mL type 1 borosilicate clear glass vial with a grey butyl stopper (not made with natural rubber) and aluminium flip off cap made of aluminium skirt fitted with a white plastic cap.

1 vial is packed in 1 carton.

IDENTIFICATION OF MENACTRA VACCINE:

MENACTRA vaccine is a clear to slightly turbid solution in unit dose vials, without preservative and free of particulate matter.

REGISTRATION NUMBER:

44/30.1/1064

NAME AND BUSINESS ADDESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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