For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory
Abridged Prescribing information

MENINGOCOCCAL (GROUPS A, C, Y AND W-135) POLYSACCHARIDE DIPHTHERIA TOXOID CONJUGATE VACCINE

MENACTRA®

COMPOSITION

MENACTRA® vaccine is an intramuscularly administered vaccine that contains *Neisseria meningitidis* serogroups A, C, Y, and W-135 capsular polysaccharide antigens individually conjugated to diphtheria toxoid protein. MENACTRA® vaccine is manufactured as a sterile, clear to slightly turbid liquid.

THERAPEUTIC INDICATIONS

MENACTRA® is indicated for active immunization to prevent invasive meningococcal disease caused by *N. meningitidis* serogroups A, C, Y, and W-135. MENACTRA® is approved for use in individuals 9 months through 55 years of age. MENACTRA® vaccine may not protect all recipients against vaccine serogroups. MENACTRA® vaccine is not indicated for the prevention of meningitis caused by other microorganisms or for the prevention of invasive meningococcal disease caused by *N. meningitidis* serogroup B

DOSAGE AND ADMINSITRATION

Withdraw the 0.5 mL dose of vaccine from the single dose vial using a sterile needle and syringe. MENACTRA® vaccine is administered as a 0.5 mL dose by the intramuscular injection. 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, Menactra® vaccine is given as a single dose.. A single booster dose may be given to individuals 15 through 55 years of age at continued risk for meningococcal disease, if at least 4 to 6 years have elapsed since the prior dose.
Do not administer this product intravenously, subcutaneously, or intradermally.

SAFETY RELATED INFORMATION:

CONTRAINDICATIONS

Severe allergic reaction (eg, anaphylaxis) after a previous dose of a meningococcal capsular polysaccharide-, diphtheria toxoid- or CRM_{197}- containing vaccine, or to any component of MENACTRA® vaccine.

Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Lactation

Risk Summary

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Menactra and any potential adverse effects on the breastfed child from Menactra. Data are **not available to assess the effects of Menactra on the breastfed infant or on milk production/excretion.**

Pediatric Use
Menactra is not approved for use in infants under 9 months of age. Available data show that infants administered three doses of Menactra (at 2, 4, and 6 months of age) had diminished responses to each meningococcal vaccine serogroup compared to older children given two doses at 9 and 12 months of age.

Geriatric Use
Safety and effectiveness of Menactra vaccine in adults older than 55 years have not been established.

WARNING AND PRECAUTIONS

Guillain-Barré Syndrome
Persons previously diagnosed with Guillain-Barré Syndrome (GBS) may be at increased risk of GBS following receipt of MENACTRA® vaccine. The decision to give MENACTRA® vaccine should take into account the potential benefits and risks. GBS has been reported in temporal relationship following administration of Menactra vaccine.

Altered Immunocompetence

- **Reduced Immune Response**

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to Menactra.

- **Complement Deficiency**

Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by N meningitidis, including invasive disease caused by serogroups A, C, Y and W-135, even if they develop antibodies following vaccination with Menactra.

Syncope
Syncope (fainting) has been reported following vaccination with MENACTRA® vaccine. Procedures should be in place to prevent falling injury and manage syncopal reactions.

ADVERSE REACTIONS

Serious Adverse Events in All Safety Studies
Serious adverse events (SAEs) were reported during a 6-month time period following vaccinations in individuals 9 months through 55 years of age. In children who received MENACTRA® vaccine at 9 months and at 12 months of age, SAEs occurred at a rate of 2.0% - 2.5%. In adolescents and adults, SAEs occurred at a rate of 1.3% following booster vaccination with Menactra.

For full prescribing information, please contact Sanofi Pasteur India Pvt. Ltd., Sanofi House, C.T.S No. - 117-B, L & T Business Park, Saki Vihar Road, Powai, Mumbai 400072.

Source: 1) US PI, v0.4 dated 26th April 2018
2) CCDS v14 dated 23rd May 2017

Updated: Nov 2019