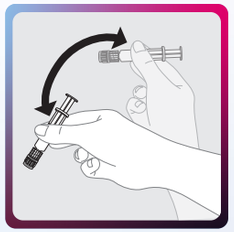
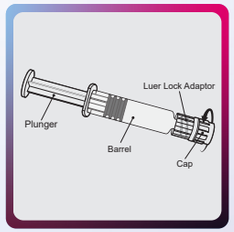
A simple guide to preparing PENMENVY

PENMENVY is supplied as one vial of Lyophilized MenACWY Component (powder) and one prefilled syringe of MenB Component (liquid) which must be combined before administration. Use only the supplied MenB Component to reconstitute the Lyophilized MenACWY Component.

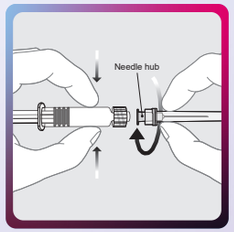
1 Prep



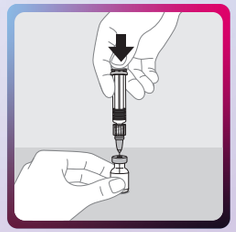
Invert the prefilled syringe of the MenB Component multiple times to form a homogeneous suspension. Do not use the prefilled syringe of the MenB Component if it cannot be resuspended.



Hold the syringe by the barrel. Unscrew the syringe cap by twisting it counterclockwise.



Connect the hub of a sterile needle to the Luer Lock Adaptor of the prefilled syringe of the MenB Component and rotate a quarter turn clockwise until it locks.

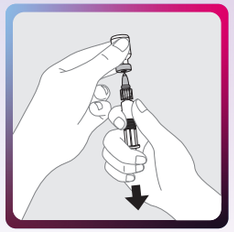


Cleanse the vial stopper of the Lyophilized MenACWY Component. Slowly transfer the entire contents of the syringe into the vial containing the Lyophilized MenACWY Component.

2 Swirl

Without removing the needle from the vial, swirl the vial gently until powder is completely dissolved. Do not invert the vial or shake vigorously.

3 Withdraw



After reconstitution, invert the vial and withdraw the entire contents.

PENMENVY is a white opalescent suspension. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exist, PENMENVY should not be administered.

Indication

PENMENVY is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y in individuals 10 through 25 years of age.

Important Safety Information for PENMENVY

- Do not administer PENMENVY to individuals with a severe allergic reaction (e.g., anaphylaxis) to a previous dose of PENMENVY, to any component of this vaccine, or to any other diphtheria toxoid-containing vaccine
- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following the administration of PENMENVY
- Syncope (fainting) has occurred in association with administration of PENMENVY. Procedures should be in place to avoid injury from fainting
- Vaccination with PENMENVY may not protect all vaccine recipients and may not provide protection against all meningococcal serogroup B strains
- Immunocompromised persons, including those receiving immunosuppressive therapy, may have reduced immune responses to PENMENVY
- Individuals with certain complement deficiencies and individuals receiving treatment that inhibits terminal complement activation are at increased risk for invasive disease caused by *N. meningitidis*, including disease caused by serogroups A, B, C, W, and Y, even if they develop antibodies following vaccination with PENMENVY
- Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of a U.S.-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision by the healthcare professional to administer PENMENVY to persons with a history of GBS should take into account the expected benefits and potential risks
- The most commonly reported (≥10%) solicited adverse reactions in individuals aged 10 through 25 years after Dose 1 and Dose 2, respectively, were pain at the injection site (92% and 88%), fatigue (51% and 42%), headache (42% and 36%), myalgia (15% and 12%), nausea (15% and 10%), erythema (13% and 12%), and swelling (13% and 12%). The most commonly reported (≥10%) solicited adverse reactions in MenACWY conjugate vaccine-experienced individuals aged 15 through 25 years after Dose 1 and Dose 2, respectively, were pain at the injection site (80% and 74%), headache (41% and 33%), fatigue (40% and 33%), myalgia (15% and 13%), and nausea (15% and 12%)

Please see full Prescribing Information for PENMENVY at PENMENVYhcp.com.

Reference: Prescribing Information for PENMENVY.

PENMENVY
Meningococcal Groups A, B, C, W, and Y Vaccine