

Instruction for the use of Focetria® Multi Dose Vials

1. Ensure that cold chain conditions between 2° and 8° C (36° and 46° F) have been maintained in the refrigerator where the vaccine has been stored. The vaccine must not be frozen.
2. Before first use of a multi-dose vial (MDV), check the expiry date and write down on the vial, the date and time of opening.
3. Between uses, return the MDV to the recommended storage conditions between 2° and 8° C (36° and 46° F). Although Focetria in MDV has a preservative that prevents microbial contamination, the MDV should preferably be used within 24 hours after first opening. Preliminary data suggest that MDV could be used up to a maximum of 72 hours after first withdrawal, although such pro-longed storage periods should not be the preferred option.
4. If the MDV has been previously opened, check the expiry date, opening date and time. Do not use if more than 72 hours from the first opening.
5. Focetria in MDV appears as a milky white suspension. Inspect the vial visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. If either of these conditions exists, the vaccine should not be administered.
6. Prior to administration, the vaccine should be allowed to reach room temperature.
7. Gently shake the MDV preparation each time before withdrawing a dose of vaccine.
8. Cleanse the rubber access diaphragm of the MDV with 70% alcohol (such as alcohol swabs) before inserting a needle into the MDV.
9. Each vaccine dose of 0.5 ml should be withdrawn into a sterile syringe for injection, using an aseptic technique (i.e. to prevent microbial contamination). A MDV allows withdrawing 10 doses of 0.5 ml vaccine.
It is recommended that small syringes (0.5 ml or 1 ml) are used to minimize any product loss.
10. Discard the vaccine if you believe that sterility has been compromised.
11. The vaccine should be given as an intramuscular injection, preferably into the deltoid muscle. For subjects with small muscle mass (e.g. infants or young children) the vaccine can be administered into the anterolateral thigh. Appropriate needles for intramuscular injections should be used, usually having a length of 25 mm (1 inch).
12. The vaccine should not be administered intravascularly.
13. Sterile syringes and needles should be used for each injection to prevent transmission of infectious agents from one person to another.
14. Once the injection has been performed, the needle should not be recapped and the device should be disposed of properly in approved sharp disposal containers.

15. At the end of the day, any remaining vaccine in syringes or waste material should be duly discarded. Vaccine that has been drawn up and not administered should not be used on subsequent days; an MDV that has not been completely used at the end of the day should be kept in the refrigerator between 2° and 8° C (36° and 46° F), but should preferably be used within 24 hours of the first opening (check the date and the time written down on the vial, as indicated in point 2). Preliminary data suggest that MDV could be used up to a maximum of 72 hours after first withdrawal, although such pro-longed storage periods should not be the preferred option.

Instruction for the use of Focetria® Pre-filled Syringes

1. Ensure that cold chain conditions between 2° and 8° C (36° and 46° F) have been maintained in the refrigerator where the vaccine has been stored.
The vaccine must not be frozen.
2. Focetria in pre-filled syringe (PFS) appears as a milky white suspension.
Inspect the PFS visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. If either of these conditions exists, the vaccine should not be administered.
3. The PFS contains 0.5 ml of vaccine and is provided with a 25 mm (1 inch) staked needle attached.
4. Prior to administration, the vaccine should be allowed to reach room temperature.
5. Gently shake the PFS preparation.
6. The vaccine should be given as an intramuscular injection, preferably into the deltoid muscle. For subjects with small muscle mass (e.g. infants or young children) the vaccine can be administered into the anterolateral thigh.
7. The vaccine should not be administered intravascularly.
8. Once the injection has been performed, the needle should not be recapped and the device should be disposed properly in approved sharp disposal containers.