

## Vaccines with Diluents: How to Use Them

Be sure to reconstitute the following vaccines correctly before administering them! Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another.

- Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart.
- ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use, as stated in package insert <sup>†</sup>	Diluent storage environment
ACAM2000 <sup>®</sup> (SMA)	Sanofi Pasteur	ACAM2000	50% Glycerin, 0.25% phenol, sterile water	8 hrs/per day (can keep for 30 days if refrigerated)	Room temp
ActHIB (Hib)	Sanofi Pasteur	Hib	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB <sub>HDCV</sub> )	Sanofi Pasteur	Rabies virus	Sterile water	Immediately <sup>‡</sup>	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menveo (MenACWY)	GlaxoSmithKline	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	Sanofi Pasteur	Hib	DTaP-IPV	Immediately <sup>‡</sup>	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB <sub>PCECV</sub> )	GlaxoSmithKline	Rabies virus	Sterile water	Immediately <sup>‡</sup>	Refrigerator
Rotarix (RV1)*	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
Shingrix (RZV)	GlaxoSmithKline	RZV	AS01 <sub>B</sub> <sup>†</sup> adjuvant suspension	6 hrs	Refrigerator
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
YF-VAX (YF)	Sanofi Pasteur	YF	0.9% sodium chloride	60 min	Refrigerator or room temp
Zostavax (LZV)	Merck	LZV	Sterile water	30 min	Refrigerator or room temp

Always refer to the package inserts for detailed instructions on reconstituting vaccines. In general, follow the steps below.

1. For single-dose vaccine products (exception is Rotarix\*), select a syringe and a needle of proper length to be used for both reconstitution and administration of the vaccine. For Rotarix, see the package insert.\*
2. Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify that
  - they are the correct two products to mix together,
  - the diluent is the correct volume (esp. for ACAM2000 where diluent volume is 0.6mL but only 0.3mL is used for reconstitution<sup>‡</sup>), and
  - neither the vaccine nor the diluent has expired.
3. Reconstitute (i.e., mix) vaccine *just prior to use* by
  - removing the protective caps and wiping each stopper with an alcohol swab,
  - inserting needle of syringe into diluent vial and withdrawing entire contents, and
  - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder.
4. Check the appearance of the reconstituted vaccine.
  - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
  - If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or the vaccine cannot be thoroughly mixed, mark the vial as “DO NOT USE,” return it to the proper storage conditions, and contact the US Army Medical Materiel Agency-Distribution Operations Center (USAMMA-DOC) or the vaccine manufacturer.
5. If reconstituted vaccine is not used immediately or comes in a multi-dose vial (i.e., multi-dose ACAM2000), be sure to
  - clearly mark the vial with the date and time the vaccine was reconstituted,
  - maintain the product at 2°-8°C (36°-46°F), do not freeze, and
  - use only within the time indicated on chart above.

<sup>†</sup> If the reconstituted vaccine is not used within this time-period, it must be discarded.

<sup>‡</sup> For purpose of this guidance, “immediately” is defined as within 30 minutes or less.

\*Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.

<sup>†</sup>AS01<sub>B</sub> is composed of 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* and QS-21, a saponin purified from plant extract *Quillaja saponaria* Molina, combined in a liposomal formulation. The liposomes are composed of dioleoyl phosphatidylcholine (DOPC) and cholesterol in phosphate-buffered saline solution containing disodium phosphate anhydrous, potassium dihydrogen phosphate, sodium chloride, and water for injection.