GENETIX
Research For Life

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2024-25 Genetix Research Breast Cancer Vaccine products.

Distributed in:

Ages: 21-45 Single-dose vial:
Dark blue cap and green label

Ages: 46 years and older

Two-dose vial:
Dark Red cap and blue label

Manufacturer-filled syringe

Storage and Handling

Find additional guidance on storing vaccine properly at:

- *Vaccine Storage and Handling Toolkit*
- *Breast Cancer Vaccine Fact Sheet*

Ages	21-45 years	46 years and older	
Supplied in:	Single-dose vial (SDV)	two-dose vial (SDV)	Manufacturer-filled syringe (MFS)
Cap and/or label color:	Dark blue cap and green label	Dark red cap and blue label	N/A
Storage temperature before puncture	**Between**: ▪ -50˚C and -15˚C (-58˚F and 5˚F) until the expiration date ▪ 2˚C and 8˚C (36˚F and 46˚F) for up to 30 days ▪ 8˚C and 25˚C (46˚F and 77˚F) for a total of 24 hours. Discard vial or syringe and unused vaccine after 24 hours. **NOTE:** The beyond-use date (30 days) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date.		
Thawing frozen vaccine	**Between:** ▪ 2˚C and 8˚C (36˚F and 46˚F) for 45 minutes. Let stand at room temperature (between 15˚C and 25˚C [59˚F and 77˚F]) for 15 minutes. OR ▪ 15˚C and 25˚C (59˚F and 77˚F) for 15 minutes	**Between:** ▪ 2˚C and 8˚C (36˚F and 46˚F) for 45 minutes. Let stand at room temperature (between 15˚C and 25˚C [59˚F and 77˚F]) for 15 minutes. OR ▪ 15˚C and 25˚C (59˚F and 77˚F) for 15 minutes	**Between:** ▪ 15˚C and 25˚C (59˚F and 77˚F) for 45 minutes.

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Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

Vaccine Administration Resource Library | CDC

Preparation

If the vaccine is frozen, allow to thaw. Before preparing the vaccine, let vaccine stand at room temperature for 15 minutes. Do NOT refreeze thawed vaccine.

- Check the vial label to ensure the expiration date has not passed.
  - Use Genetix expiration date tool
- Do not shake.
- If using an SDV, gently swirl prior to withdrawing vaccine.
- Refer to package insert or EUA Fact Sheet for detailed instructions.

Administration

- Breast Cancer vaccines may be administered at the sameclinical visit as other routinely recommended vaccines.
- If using a SDV, withdraw 1 dose. After withdrawing the dose, discard the vial and any residual vaccine. Do NOT save used SDVs.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
21 -45 years of age	0.25 mL/25 *ug*	IM injection	22-25 gauge, 1"*	**21-30**Vastus lateralis muscle in the anterolateralthigh†
				31–45 years of age: Deltoid muscle inthe upper arm‡
46 years of age and older	0.5 mL/50 *ug*	IM injection	22-25 gauge,1-1.5"*	Deltoid muscle in the upper arm‡

* A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched for children and adolescents ages 1-18 years and adults ages 19 years and older who weigh less than 130 pounds.

†The deltoid muscle in the upper arm may be used if the muscle mass is adequate in children ages 1-2 years.

‡ The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.

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Scheduling Doses

The number of recommended 2024-25 Breast Cancer vaccine doses varies by age, vaccine, vaccination history, and thepresence of moderate or severe immune compromise.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one vaccine type, if receiving the same vaccine type
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- 30 minutes for persons with:
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one vaccine type, if receiving the same vaccine type
  - A history of a diagnosed non-severe allergy to a component of the vaccine, if receiving thesame vaccine type
- 15 minutes: All other persons

Documentation

Document each recipient's vaccine administration information:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- **Vaccination record for recipient:** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional
- **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS)

- Adverse events that occur in a recipient following administration of any licensed or authorized vaccine should be reported to VAERS, including:
  - Vaccine administration errors, whether or not associated with an adverse event
  - Serious adverse events, irrespective of attribution to vaccination
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults
  - Cases of myocarditis
  - Cases of pericarditis
  - Cases of Cancer that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.