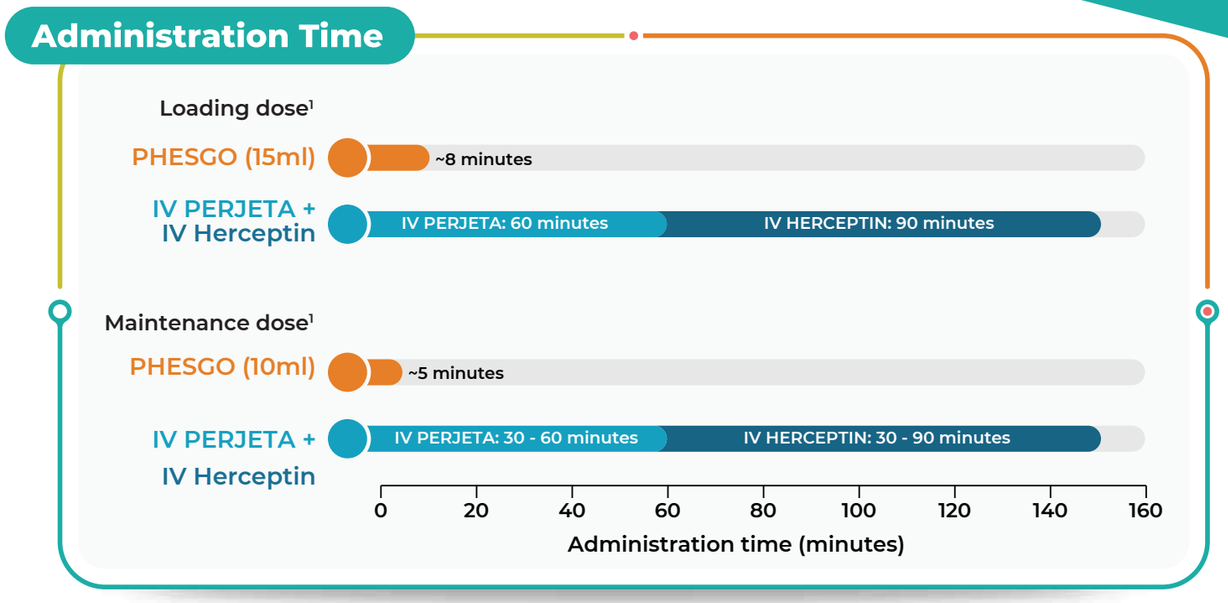
PHESGO®
PERTUZUMAB-TRASTUZUMAB

Roche

Phesgo reolutionizes the treatment all HER2+ indications, allowing more flexibility and time for patients and improving healthcare system efficiency.

PHESGO DOSING AND DMINISTRATIO GUIDE

The fixed-dose combination of Pertuzumab and Trastuzumab in one vial for subcutaneous use



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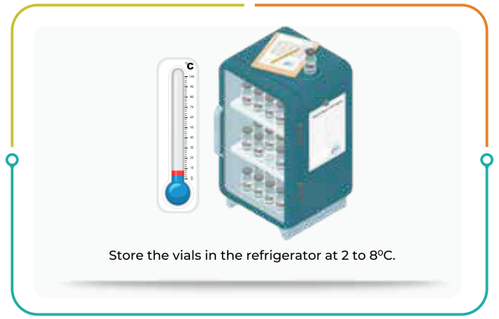
Preparing and administering the fixed-dose combination: A step-by-step guide

VIAL STORAGE[1]

The fixed-dose combination(PHESGO) is supplied in sterile, preservative-free, single- dose vials for subcutaneous administration. Store in refrigerator at 2-8°C. Protect from light. Do not freeze[1].



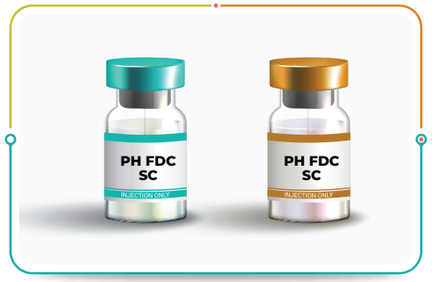
Store the vials in the refrigerator at 2 to 8°C.

CHECKING THE VIAL[1]

To prevent errors, check the vial labels to ensure that the drug being prepared and administered is PHESGO and not Pertuzumab IV, or Trastuzumab IV or SC PHESCO is clear to opalescent and colorless to slightly brownish.

- Inspect the vial for particulate matter and discoloration prior to administration, Do not use vial if particulates or discoloration is present
- Do not shake
- Select the right vial depending on whether this is a loading dose or maintenance dose, and check the expiration date

To prevent errors, check the vial labels to ensure that the drug being prepared and administered is the fixed-dose combination



The fixed-dose combination comes in 2 formulations 1st Loading dose: 15mL of solution in a 20 CC vial.

Maintenance dose: 10 mL of solution in a 15 CC vial.

PH FDC SC: fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection

* Images used are for Illustration Purposes.

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PREPARING THE INJECTION[1]

The loading and maintenance doses are ready-to-use for subcutaneous injection and shoul not be diluted. Please bring PHESGO to room temperature (maximum 30°C) prior to administering. Only a trained healthcare professional should administer PHESGO.

- Transfer PHESGO from the vial to the injection syringe. Attach a transfer needle to the syringe. Remove and discard the vial cap. Wipe the vial stopper with alcohol swab and allow it to dry naturally. Hold the syringe by the barrel, insert the transfer needle into the center of the vial cap at a 90-degree angle
- Remove the needle, after withdrawing the entire content from the vial. Then re- move the transfer needle from the syringe. Put patient information sticker on the syringe.
- If the solution is not to be injected right away, replace the transfer needle with a sy ringe closing cap. To avoid needle clogging, don't attach a hypodermic needle at the time of administration.
- You may store PHESGO in the refrigerator for up to 24 hours after filling the syringe. Remove the solution from the fridge in advance, as it should be administered at room temperature.
- Discard the transfer needle or the syringe stopper after replacing it with a sterile subcutaneus injection needle. Suitable injection needle for this solution is be- tween 25G-27G and lengths between 3/8"(10 mm)-5/8"(16 mm)

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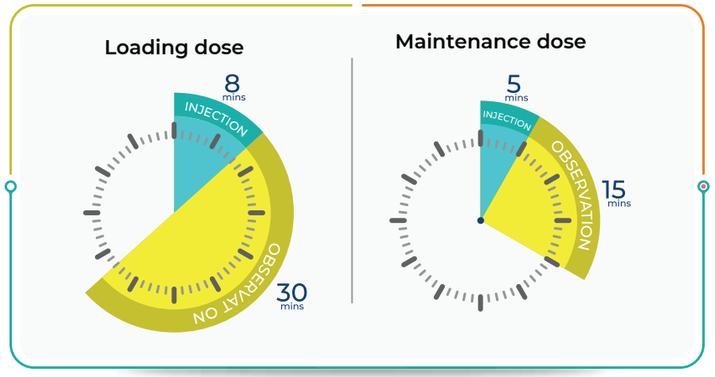
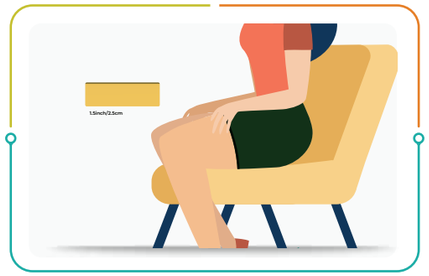
PREPARING THE PATIENT[1]



- Ask the patient to wear loose clothing that would allow easy access to the thigh area. Ideally the patient should bring the ONBOARDING KIT provided which con- tains the blanket with a velcro slit
- PHESGO is not recommended during pregnancy and lactation due to risk of embryo-fetal death and birth defects
- Entire injection and observation process would take up around 38 minutes for the loading doseand 20 minutes for the maintenance dose
- PHESGO should be administered via subcutaneous injection in the thigh only. PHESGO is not intended for intravenous administration.



- Make sure you and the patient are comfortable in the same position for approximately 5 to 8 minutes
- Alter injection site between the left and right thigh. Don't split the dose between two syringes or two sites of administration. New injection site must at least 1 inch, or 2.5 cm, from the previous site
- Choose an area of healthy skin that is not red, bruised, tattooed, tender, or hard. During treatment other subcutaneous medications should preferably be injected at different sites
- PHESGO is never administered in the abdomen since it may lead to a lower concentrations

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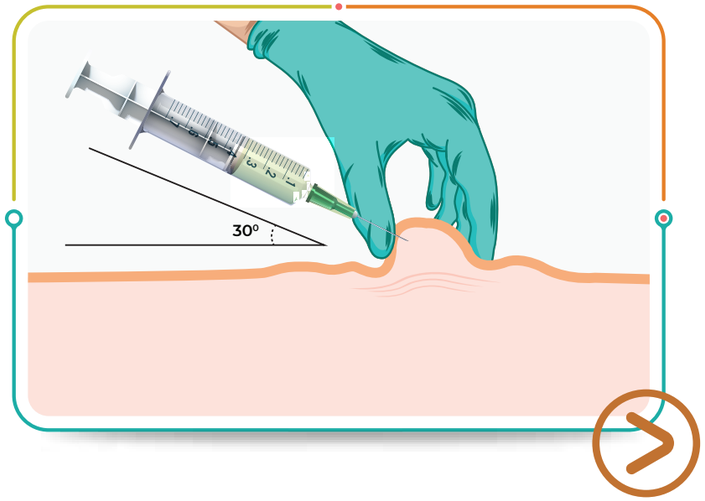
ADMINISTERING THE INJECTION[1]

- Prepare the injection site on thigh following standard aseptic procedures
- Begin with pinching the skin of the thigh with one hand to create a fold. It allows the injection to get into the subcutaneous space and not into the muscle tissue. Inject and maintain the needle at an angle of about 30 degrees
- Administer the dose at a rate of not more than 2mL/min, the loading dose take approximately 8 minutes to administer, while the maintenance doses will take approximately 5 minutes
- Ensure the full content in the syringe is injected into the subcutaneous tissue. Wait for 10 seconds after the complete dose has been administered before withdrawing the needle.
- Make sure that medication to treat reactions, as well as emergency equipment, is available for immediate use
- If at any point while injecting PHESGO, patient feels pain or discomfort, ease off the injection before continuing again. Keep the needle in place and check to make sure that the needle is at the right 30 degree angle
- IThe injection may also be slowed or paused if the patient experiences a significant injection related reaction. The injection should be discontinued immediately if the patient experiences a serious hypersensitivity reaction (e.g. anaphylaxis)
- After the loading dose, the patient should be observed for a minimum of 30 minutes, for signs of hypersensitivity symptoms or administration-related reactions. After the maintenance doses, the patient should be observed for a minimum of 15 minutes
- Please follow Adverse Drug Reporting guidelines as applicable



IMPORTANT INFORMATION

Patients should be observed for injection-related reactions and hypersensitivity reactions. Observation period should start following administration of PHESGO and be completed prior to any subsequent administration of chemotherapy. Please follow Adverse Drug Reporting guidelines as applicable.

CONTRAINDICATIONS

PHESCO is contraindicated in patients with known hypersensitivity to pertuzumab, trastuzumab or hyaluronidase, or to any of its excipients.

INJECTION RELATED REACTIONS(IRRS)

PHESGO has been associated with injection-related reactions. Close observation of the patient during and for 30 minutes after administration of the loading dose and during and for 15 minutes following the administration of the maintenance dose of PHESCO is recommended. If a significant injection-related reaction occurs, the injection should be slowed down or paused and appropriate medical therapies should be administered. Patients should be evaluated and carefully monitored until complete resolution of signs and symptoms. Permanent discontinuation should be considered in patients with se- vere injection-related reactions. Although fatal outcomes resulting from injection-re- lated reactions have not been observed with PHESGO, caution should be exercised as fatal infusion related-reactions have been associated with intravenous Pertuzumab in combination with intravenous trastuzumab and chemotherapy.

Please refer full prescribing information for more details

REFERENCES

1. Product Information IND Phesgo® January 2022

2. PHESCO Summary of Product Characteristics. January 2020 (EMA)

http://bit.ly/Roche_Phesgo_PI

PHESGO®
PERTUZUMAB-TRASTUZUMAB

Please use the QR code/cick on the link for the latest Prescribing Information (PI). For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Please read full prescribing information before usage.

Details of Permission or License Number with date:

Permission No. IMP/BIO/21/000082 dated 01-Oct-2021

Date of Revision:

Current at January 2022, Version 2.0 M-IN-00003034

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