Phesgo Compatibility and Administration Recommendations

This article responds to your request for information on Phesgo® (pertuzumab, trastuzumab, and hyaluronidase) subcutaneous injection and administration recommendations.

Please refer to the locally approved Phesgo prescribing information for recommendations on administering Phesgo. Any deviation from this information is considered off-label and any treatment decisions based on such deviations are the full responsibility of the prescribing physician.

In brief

- There is no requirement to use an in-line filter during Phesgo administration. The use of an in-line filter is not recommended by Roche/Genentech.
- Roche/Genentech does not have a recommendation on the use of a butterfly or winged needle to administer Phesgo.
    - A technical feasibility study demonstrated physical and chemical compatibility of Phesgo with two infusions systems, both of which contain butterfly needles.
    - Infusion systems can retain a volume of the drug product being administered. It is the user's responsibility to ensure the entire dose is administered to the patient.
- Roche/Genentech does not have a recommendation on the administration of Phesgo via a syringe driver or pump.
    - An experimental pressure characterisation study was conducted to simulate the administration of a Phesgo 10 mL solution with two syringe drivers.

Compatibility of materials and Phesgo

No incompatibilities between Phesgo and polypropylene (PP), polycarbonate (PC), polyurethane (PU), polyethylene (PE), polyvinyl chloride (PVC) and fluorinated ethylene polypropylene (FEP) have been observed.[1]

Recommendations on the use of in-line filters

Phesgo is formulated as a liquid solution for injection and does not require reconstitution.[1]

There is no requirement to use an in-line filter during Phesgo administration.[1] The use of an in-line filter is not recommended by Roche/Genentech.

The Phesgo manufacturing process includes two filtration steps with a polyvinylidene difluoride (PVDF) filter with 0.2µm pore size.[2]

Recommendations on the use of butterfly needles

Roche/Genentech does not have a recommendation on the use of a butterfly or winged needle to administer Phesgo.[1] Refer to the locally approved prescribing information for further recommendations on appropriate sized needles for administration of Phesgo.

In-use compatibility study

In a technical feasibility study, Roche tested the in-use stability and compatibility of Phesgo with standard administration materials.[3] As part of the study, the compatibility of Phesgo was assessed with a SC infusion set and a safety catheter system, both of which include a butterfly needle:

- BD Saf-T-Intima safety catheter system with Y adaptor — Reference number 383319.
- Ypsomed Orbit SC infusion set — Reference number O2461, 6 mm cannula, 60 cm tubing.

The results from the study demonstrated physical and chemical compatibility of Phesgo with both devices.[3]

Hold-up volume assessment study

It is the healthcare professional's responsibility to ensure the entire dose is administered to the patient. Infusion sets or systems can retain a volume of the drug product being administered, known as the hold-up volume.

An internal technical study assessed the hold-up volume of the Ypsomed Orbit SC infusion set when used to administer Phesgo.[4] The study found that the Ypsomed Orbit allowed delivery of the entire dose of Phesgo, after withdrawal from the vial using a syringe and transfer needle. The acceptance criteria for this study was a hold-up volume ≤0.50mL. For all tested samples, the hold-up volume fulfilled the acceptance criterion.[4]

Recommendations on the use of syringe drivers

Roche/Genentech does not have a recommendation on the administration of Phesgo via a syringe driver or pump.[1]

Flow rate experimental study

In an experimental pressure characterisation study, Roche simulated the administration of a Phesgo 10 mL solution with two syringe drivers:[5]

- B. Braun Perfusor Space — Reference number 8713030
- Terumo Terufusion — Reference number TE-SS800EN1

Both syringe pumps were tested with Ypsomed Orbit SC infusion sets. Backpressure of the skin was not considered in the measurements, and the test simulated injection into the air. The simulation found that both syringe pumps were suitable for automated flow rate control of Phesgo while using Ypsomed Orbit infusion sets without triggering the occlusion alarm.[5]

References

1. Roche Internal Regulatory Report (Phesgo CDS 3.0). Accessed 21 June 2023.
2. Internal Roche Correspondence. Accessed 11 May 2023.
3. Roche Internal Technical Report (TEC-0172225). Accessed 21 Aug 2023.
4. Roche Internal Technical Report (TEC-0173596). Accessed 21 Aug 2023.
5. Roche Internal Technical Report (2018-363). Accessed 23 August 2023.