Prevymis (letermovir) concentrate for solution for infusion - Essential to administer through sterile 0.2 micron or 0.22 micron polyethersulfone (PES) in-line filter

Dear Healthcare professional,

Merck Sharp & Dohme B.V. in agreement with the European Medicines Agency and the <National Competent Authority > would like to inform you of the following important prescribing information:

Summary

- **The diluted solution of Prevymis (letermovir concentrate for solution for infusion 20 mg/mL) MUST be infused through a sterile 0.2-micron or 0.22-micron polyethersulfone (PES) in-line filter.**
- **Inspect the vial contents for discoloration and particulate matter. The concentrate is a clear and colorless solution and may contain a few product-related small translucent or white particles. Once diluted, the solution for infusion is clear and ranges from colorless to yellow.**
- **Do not use if the concentrate or diluted solution is cloudy, discolored, or contains matter other than a few small translucent or white particles.**
- **Do not use Prevymis concentrate for solution for infusion with IV bags and infusion set materials containing polyurethane or diethylhexyl phthalate (DEHP). Materials that are phthalate-free are also DEHP-free.**

Background on the safety concern

Prevymis concentrate for solution for infusion may contain product-related small translucent or white particles. Use of a sterile 0.2-micron or 0.22-micron PES in-line filter prevents possible administration of particles that have been seen in vials of Prevymis injection. Administration through a sterile 0.2-micron or 0.22-micron PES in-line filter has no impact on Prevymis dosage.

Administration of Prevymis diluted solution always requires the use of a sterile 0.2 micron or 0.22 micron PES in-line filter, regardless of whether these product-related particles are visible in the vial or diluted solution.

Please ensure that staff and any provider in your institution who may be involved in the reconstitution and administration of Prevymis carefully follow the reconstitution and administration instructions in the summary of product characteristics (SmPC) and the package leaflet (PIL) for Prevymis.

Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). Prevymis may be administered orally, with Prevymis 240 mg or 480 mg tablets, or intravenously, using Prevymis concentrate for solution for infusion after suitable dilution.

PREPARATION AND ADMINISTRATION OF INTRAVENOUS PREVYMIS (letermovir) concentrate for solution for infusion

- Prevymis must be diluted prior to intravenous (IV) use according to the instructions in the SmPC.
- Inspect the vial contents for discoloration and particulate matter prior to dilution. Prevymis concentrate for solution for infusion is a clear and colorless solution and may contain a few product-related small translucent or white particles.
- Do not use the vial if the solution is cloudy, discolored, or contains matter other than a few small translucent or white particles.
- Do not use Prevymis concentrate for solution for infusion with IV bags and infusion set materials containing polyurethane or the plasticizer diethylhexyl phthalate (DEHP). Materials that are phthalate-free are also DEHP-free.
- Once diluted, the solution of Prevymis is clear and ranges from colorless to yellow. Variations of color within this range do not affect the quality of the product.
- **Discard the diluted solution if the solution is cloudy, discolored, or contains matter other than a few small translucent or white particles.**
- **The diluted solution must be administered through a sterile <u>0.2-micron or 0.22-micron PES</u> in-line filter.**

Please refer to the SmPC for full prescribing information.

Call for reporting

▼This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions. <Details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system >

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Annexes

<List of 0.2- or 0.22-micron PES filters available for use in the EU markets will also be provided>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Prevymis (letermovir) concentrate for solution for infusion
Marketing authorisation holder(s)	Merck Sharp & Dohme B.V.
Safety concern and purpose of the communication	Prevymis (letermovir) concentrate for solution for infusion: Essential to administer through sterile 0.2 micron or 0.22 micron polyethersulfone (PES) in-line filter
DHPC recipients	Transplant specialist physicians, centres/clinics performing stem cell transplantation, infectious disease specialists Target groups should be further defined on national level, depending on national health care systems
Member States where the DHPC will be distributed	Austria, Denmark, Germany

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	28 May 2020
Submission of translated DHPCs to the national competent authorities for review	CHMP opinion + 5 calendar days
Agreement of translations by national competent authorities	CHMP opinion + 14 calendar days
Dissemination of DHPC	DHCP dissemination will be coordinated with the distribution of Prevymis IV to markets that is anticipated by late 3Q-2020