



An oral liquid of an established antiviral (Reformulating)

ABOUT

Valacyclovir powder for suspension is a differentiated formulation of a well-established antiviral designed for patients who have difficulty swallowing tablets. It aims to improve access, dosing accuracy, and adherence across pediatric, geriatric, and immunocompromised populations through a more practical oral presentation.

STAGE

Hyloris has submitted an NDA to the U.S. FDA. A Complete Response Letter was received following manufacturing-site observations identified during an FDA inspection at the CDMO responsible for the product. No product-specific deficiencies were raised. Hyloris is evaluating next steps with the current CDMO, which is addressing the FDA observations, as well as alternative manufacturing solutions; this may shift launch timing into 2027.

INDICATION

Valacyclovir is indicated for herpes virus infections. Adult patients label uses include cold sores, initial and recurrent genital herpes, suppressive therapy and reduction of transmission of genital herpes, and shingles. Pediatric patient label uses include cold sores and chickenpox.

BENEFIT

Currently, valacyclovir is available in oral solid form. This oral liquid formulation is designed to support treatment of infections such as shingles and chickenpox, particularly in patients who cannot easily swallow solid dosage forms. With taste-masking technology and room-temperature stability, it offers a more patient-friendly alternative to tablets and extemporaneously compounded suspensions, with the potential to improve convenience, dosing precision, and adherence.

IP RIGHTS / EXCLUSIVITY

Proprietary formulation protected by U.S. patents with expiries in 2035 and 2036, and pending patent applications in key markets with expiry expected in 2045.

Forward-Looking Statements



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HQ: Boulevard Patience Et Beaujonc N°3/1
4000 Liège, Belgium



+32(0)4 346 02 07



contact@hyloris.com
investorrelations@hyloris.com

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