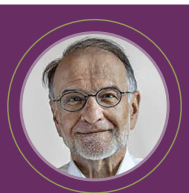
Industry Symposium sponsored by Amicus Therapeutics

This meeting is not intended for registered attendees from the UK.

Advancing our knowledge of Galafold® (migalastat) treatment and monitoring strategies

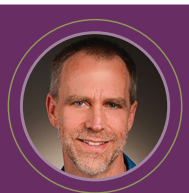
Wednesday, February 7, 2024, 6:15–7:15 AM PST
Grand Hall AB, Manchester Grand Hyatt, San Diego, USA

The journey of a person living with Fabry disease presents many challenges, from treatment initiation and monitoring to living with a multisystemic condition. Join our symposium to hear from an expert panel about the importance of a holistic approach to managing patients with Fabry disease and considerations for initiating and monitoring Galafold® (migalastat) across adult patients with confirmed Fabry disease and an amenable *GLA* variant.



Prof Daniel Bichet
University of Montreal, Quebec, Canada

Prof Derralynn Hughes
Royal Free London NHS Foundation Trust, UK



Prof Robert Hopkin
University of Cincinnati College of Medicine, USA

Dr Staci Kallish
Penn Medicine, Philadelphia, USA

This meeting is intended for healthcare professionals. This meeting is not intended for registered attendees from the UK. Amicus Therapeutics' product Galafold® (migalastat) will be discussed at this meeting.

Galafold® (migalastat) 123 mg capsule Indication and Important Safety Information

INDICATIONS AND USAGE

Galafold is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (*GLA*) variant based on *in vitro* assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse drug reactions reported with Galafold (≥10%) are headache, nasopharyngitis, urinary tract infection, nausea, and pyrexia.

DRUG INTERACTIONS

Avoid co-administration of Galafold with caffeine at least 2 hours before and 2 hours after taking Galafold.

USE IN SPECIFIC POPULATIONS

There is insufficient clinical data on Galafold use in pregnant women to inform a drug associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus.

It is not known if Galafold is present in human milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Galafold and any potential adverse effects on the breastfed child from Galafold or from the underlying maternal condition.

Galafold is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis.

The safety and effectiveness of Galafold have not been established in pediatric patients.

To report Suspected Adverse Reactions, contact Amicus Therapeutics at 1-877-4-AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information available at the Amicus booth and at https://www.amicusrx.com/pi/galafold.pdf

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