



Medicines & Healthcare products
Regulatory Agency



MHRA
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United Kingdom

gov.uk/mhra

MRS. UMA MAHESHWARI
LYRUS LIFE SCIENCES LIMITED
C/O THAKUR-CHABERT, SUITE 410, 4TH FLOOR
1 HAREFIELD ROAD
UXBRIDGE
UB8 1EX
UNITED KINGDOM

04/06/2024

Dear Mrs. Maheshwari,

GRANT / RENEWAL OF MARKETING AUTHORISATION

Our Reference:	PL 48974/0023 - 0001
Your Reference:	48974
Product:	Metformin hydrochloride Lyrus 1000 mg prolonged release tablets
Type of Procedure:	National
Submission Type:	Initial
Submission Category:	Abridged
Territory:	UK
Route:	Direct

The Licensing Authority agrees to the grant or renewal of the marketing authorisation for the above submission on the basis of the data provided. This includes any replacement and amendment of the original dossier.

In line with the Human Medicines Regulations, the Marketing Authorisation Holder should submit notification of the actual date of marketing of the product to the MHRA.

This notification should be provided by email to the following address: sunsetclause@mhra.gov.uk.

The formal documents are enclosed. These constitute evidence of authorisation. If you consider them to contain information that is incorrect or not in accordance with the dossier, please return immediately indicating any errors.

All Marketing Authorisations are subject to standard provisions contained in current medicines regulations full details of which are published on the MHRA section of its website:

<https://www.gov.uk/topic/medicines-medical-devices-blood/marketing-authorisations-variations-licensing>

Yours sincerely,

Keely Kennedy



The Human Medicines Regulations SI 2012/1916, as amended.

GRANT / RENEWAL OF MARKETING AUTHORISATION

Product: PL 48974/0023 – 0001 Metformin hydrochloride Lyrus 1000 mg prolonged release tablets

Submission Type: Initial

Granted to: LYRUS LIFE SCIENCES LIMITED
C/O THAKUR-CHABERT, SUITE 410, 4TH FLOOR
1 HAREFIELD ROAD
UXBRIDGE
UB8 1EX
UNITED KINGDOM

This Marketing Authorisation, under the above reference number is hereby granted / renewed in respect of the product named above. The Summary of Product Characteristics of the product is set out in the attached document.

The application is subject to the further provisions set out or referred to in the above Regulations.

This Marketing Authorisation, as now granted / renewed, unless previously revoked, will continue in force until the expiry date (if applicable) given below.

Grant Date: 04/06/2024

Date of Expiry: 03/06/2029

Keely Kennedy
A person authorised to sign on behalf of the Secretary of State for Health