DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

27th October 2020

Ref: 3809/DR/NDA-10/2020

INDIA

REGISTRATION OF PHARMACEUTICAL PRODUCT

We are pleased to inform you that, the drug below for which you had applied for registration in Uganda has been approved.

FILE NO	NDA REGISTRATION NUMBER	DRUG NAME	GENERIC NAME	STRENGTH	DOSAGE FORM	PACK SIZE
N746	NDA/MAL/HDP/9216	URELOG	CALCIUM-4-METHYL-2 OXO-VALERATE + CALCIUM-3-METHYL-2 OXO-BUTYRATE + CALCIUM-2- OXO-3-PHENYL PROPIONATE + CALCIUM-3-METHYL-2 OXO-VALERATE + CALCIUM-DI-2 HYDROXY (4 METHYLTHIO) BUTYRATE + L-LYSINE ACETATE + L-THREONINE + L-HISTIDINE + L-TYROSINE + L-TRYPTOPHAN + TOTAL NITROGEN CONTENT + TOTAL CALCIUM	101MG + 86MG + 68MG + 67MG + 59MG + 105MG + 53MG + 38MG + 30MG + 23MG +36MG 0.05G	FILM COATED TABLETS	1*10*10, ALU/ALU BLISTER PACK

Please note that to maintain this product on the register you will be required to pay annual retention fees as prescribed in the Statutory Instruments 2014 No. 31.

Other products manufactured by your company, including products of the same name manufactured in a different place from that applied for, may not be imported into Uganda unless specially approved by the National Drug Authority.

Registration of a drug does not exempt the applicant and/or manufacturer or his agent from any other enforceable laws of Uganda or International laws or conventions more especially the patent rights, trade marks etc.

Continuous monitoring of your products in Uganda for compliance to quality standards shall be conducted. Any change in the information submitted to the National Drug Authority for the purpose of registration must be notified to the Authority within 30 days of the change, at a prescribed fee.

Your authorised agent in Uganda will be held responsible for all technical aspects of the product(s) marketed in Uganda, including but not exclusively:

- Obligation to notify changes in the product, including labelling, package insert information etc.
- Notification of any changes in the product information with regard to any newly identified adverse or side effects, drug interactions, warning etc.
- Responsibilities of any necessary product re-call on behalf of the manufacturer or applicant.
- Certifying proforma invoices from applicant/manufacturer.

Yours faithfully,

David Nahamya
SECRETARY TO THE AUTHORITY

Copy to: Pharmacist in-charge, Harley's Uganda Limited

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OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

REGIONAL OFFICES
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DRUG NATIONAL AUTHORITY

Consider this date

FORM 3 *Regulation 14(1)*

CERTIFICATE FOR REGISTRATION OF HUMAN OR VETERINARY DRUGS, PREPARATION AND VACCINES OR OTHER IMMUNOLOGICAL PRODUCTS

NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

(Pursuant to Regulation 14(1) of The National Drug Policy and Authority (Registration) Regulations, 2014)

Date of registration: **8th September 2020**

Registration number: **NDA/MAL/HDP/9216**

Expiry date of registration: **8th September 2025**

Category of drug or preparation: Human ☒ Veterinary ☐

1. Product information

Proprietary (trade) name: **URELOG**	
Generic name (the International Nonproprietary name; for herbal product, state botanical name): **Calcium-4-methyl-2 Oxo-valerate + Calcium-3-methyl-2 Oxo-butyrate + Calcium-2- oxo-3-phenyl propionate + Calcium-3-methyl-2 oxo-valerate + Calcium-di-2 hydroxy (4 methylthio) butyrate + L-Lysine acetate + L-Threonine + L-Histidine + L-Tyrosine + L-Tryptophan + Total Nitrogen content + Total Calcium**	
Dosage form: **Film coated tablets**	Strength: **101mg + 86mg + 68mg + 67mg + 59mg + 105mg + 53mg + 38mg + 30mg + 23mg +36mg 0.05g**
Description of drug or preparation: **Capsule shaped yellow coloured film coated tablet**	
Therapeutic category: **Minerals and Amino acids**	
Indication: **Prevention or treatment of deficiencies of the corresponding Amino acids and vitamins**	

2. Approved manufacturer(s) information for the product

Production stage	*Name of manufacturer*	*Street address of Site*	*Manufacturing step*
Complete manufacture			**Complete manufacture**

3. Product shelf-life

The approved shelf-life of this product when packaged and labeled as detailed in the application and modified in subsequent correspondence is as follows.

Pack description	*Shelf-life*	*Storage conditions*
1*10*10, ALU/ALU BLISTER PACK	**24 months**	**Do not store above 30^{0}C**

4. Restrictions on sale or distribution of drug or preparation

☐ Scheduled narcotic ☒ Prescription only ☐ Pharmacy only ☐ Over-the-counter (OTC)
☐ Restricted prescription-only distribution (specify, for example, Hospitals only)

David Nahamya
SECRETARY TO THE AUTHORITY

OFFICE OF THE SECRETARY TO THE AUTHORITY