Recipharm

RPH Pharmaceuticals AB
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Sweden

8th August 2024

Eudemine Tablets (Diazoxide): Notification on storage conditions for Eudemine 50mg Tablets PL 36301/0021

Dear Healthcare Professional,

The Marketing Authorisation Holder, RPH Pharmaceuticals AB in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to notify you of the proper storage conditions for Eudemine 50mg Tablets.

Summary

Please ensure that Eudemine 50mg Tablets are stored at the following conditions:

- **Store below 25°C.**

Through routine testing we have identified that when the product is stored at 30°C / 65% relative humidity, it shows a decrease in the dissolution of the active ingredient which could potentially impact the rate the active substance is absorbed by the body if the tablets are stored above 25°C.

The packaging will be updated with these storage requirements for future batches.

Background

Eudemine belongs to a group of medicines called thiazides. These work by increasing levels of sugar in the blood.

Eudemine is used to treat a condition called 'intractable hypoglycaemia'. This is when the sugar level in your blood has been very low for a long time. A low sugar level in the blood is caused by an increase in the amount of the hormone insulin, being produced by the pancreas.

It is important for patients to take this medicine as very low blood sugar can result in unusual behaviour, (such as aggression), sweating, a fast pulse and can lead to a coma, which may occur quite suddenly.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

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Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9.00am and 5pm.

Company contact point

Please contact us if you have any questions by email: customer.care@recipharm.com or phone: +44 (0)845 023 0467.

The SmPC, Patient Information Leaflet are also available at www.medicines.org.uk/emc.

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