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Division/Dept. Medical Dept
Care of Michael Thompson
Phone +44 (0)20 88187278
Fax
E-mail Mike.thompson@external.merckgroup.com

Risk minimisation measures to avoid the risk of unintentional overdose when switching patients on Saizen powder to Saizen Solution for Injection (Somatropin)

Dear Healthcare Professional,

Saizen[®] Solution for Injection (Somatropin) was launched in Ireland in 2012 in cartridges of 6mg, 12mg and 20mg for use with the Merck Serono auto-injector easypod.

Following reports of overdose, healthcare professionals are reminded of the following risk minimisation advice:

- Patients switching to the solution from the freeze dried formulation need to have the injection settings of their easypod altered as the concentration of the 12mg and 20mg vials is 8mg/ml compared to 5.83mg/ml in the freeze-dried formulation.
- There have been reports of use where this has not happened placing patients at risk of injecting greater amounts of somatropin than prescribed.
- **To mitigate against this risk, Merck Serono recommends that patients who are switched to the solution formulation should receive a new Easypod which should be set appropriately to ensure the prescribed amount of growth hormone is injected.**

Further information

Patients who have already been switched may have the latest Easypods[™] and the correct settings but you should arrange for your SENSE nurse to confirm this as soon as possible, and we recommend that a new Easypod[™] is provided to the patient if any patients have been switched to the solution without having also been given the new Easypod[™] device.

Merck Serono (Ireland) Limited

Trading as Merck Serono

Registered in Ireland with No. 446715

Registered address

4045 Kingswood Road

Citywest Business Campus

Dublin 24

Ireland

www.merckserono.net

Róisín Molloy

Head of Business

Development (Ireland)

Phone + 353 (0)1 468 7590

Fax + 353 (0)1 466 3446

Merck Serono is a division of Merck

Directors:

Julian Bradwell

D.G. Cowling (British)

S. Becker (German)

Easypods™ can be ordered via your SENSE nurse or by contacting the Saizen Patient Support line on 1800 409 217.

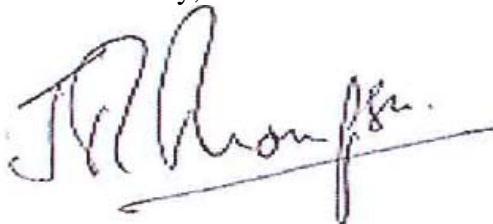
Healthcare professions are reminded to ensure that the patients are aware of the recommendations for use in the product information:

- For administration of the solution for injection of Saizen, patients should follow the instructions given in the package leaflet and in the instruction manual provided with the selected auto-injector.
- Intended users of easypod are primarily children starting from the age of 7 up to adults. Use of the devices by children should always be made under adult's supervision.

Please report suspected adverse reactions to the Irish Medicines Board using the online reporting system or the yellow card system.

For further information about this issue, please contact Merck Serono Medical Information on 1800 719881 or email medinfo.uk@merckserono.net.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Dr Michael Thompson". The signature is written in a cursive style and is positioned above a horizontal line.

Dr Michael Thompson

Interim Medical Director
Merck Serono UK & Ireland