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**Urgent Field Safety Notice**  
**Terrafor ventre plat®,**  
**Recall to the wholesaler/ distributor**

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Date: 15<sup>th</sup> September 2016

Attention:

**Details on affected device:**

Name: Terrafor ventre plat®

Dosage Form: capsules (50 capsules / packaging)

Affected batch numbers: All batches sold on the Swiss market.

Delivered batches by Iromedica AG since January 2016:

Batch-No.	MDF	EXP
H07840	2014-06	2019-05
H17620	2014-11	2019-10

**Description of the problem:**

Due to the revision of the product specification to the current pharmacopoeia and food legislation, the content of lead exceeded the new specification. Therefore, Terrafor ventre plat® entails a lack of quality.

Considering the current evidence base, an acute hazard to health is not given.

**Advise on action to be taken by the wholesaler/distributor:**

Please take action in accordance to the following steps:

1. Identify and quarantine the device
2. Stop distribution of device
3. Fill out confirmation form and send back to distributor
4. Return all available packages to distributor immediately but latest until 31<sup>st</sup> December 2016

**Address of returned packages/products:**

Galliker Transport AG  
Lager Iromedica AG  
Knotternstrasse 9  
9422 Staad

**Contact reference person:**

Dr. R. Renato Kaiser  
Iromedica AG  
Oberstr. 222  
9014 St. Gallen  
Phone: 071 274 18 00  
Email: Renato.Kaiser@iromedica.ch

The undersign confirms that this notice has been notified the appropriate Regulatory Agency (Closing paragraph)



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Dr. R. Renato Kaiser