

TO WHOM IT MAY CONCERN

St. Gallen, 21 February 2018

Declaration by the Marketing Authorization Holder

Ferinject:

We, Vifor (International) Inc., herewith confirm that Ferinject® is the originator product. It is an innovative pharmaceutical product comprising the active ingredient 'ferric carboxymaltose' used for intravenous (i.v.) treatment of iron deficiency when oral iron preparations are ineffective or cannot be used.

As an innovative product, the active ingredient 'ferric carboxymaltose' contained in Ferinject® is patent protected worldwide (e.g. Europe, USA, Japan, India, Russia, China, Korea, Brazil,...).

In particular, **ferric carboxymaltose is patent protected in Chile** by the Chilean patent No. 51553 originally filed with the application number 2118/2003, and which will expire the **20/10/2023**. The corresponding certificate is attached herewith as annex. In addition, we have filed a Patent Term Extension application no. is A/2017/003396 that might extend the corresponding Chilean Patent by up to 5 years.

Ferinject® was first authorized in the Netherlands in July 2007 (Marketing Authorization number 33865) and Switzerland in November 2007 (Marketing Authorization number 57851).

Venofer:

We, Vifor (International) Inc., herewith confirm that Venofer® is the originator product and the first approved drug containing 'iron sucrose' as an active ingredient. It was first authorized in Switzerland the 6th December 1949 (marketing authorization number 15398).

We furthermore confirm that no Patent applications were ever filed to protect the 'iron sucrose' contained in Venofer®. Therefore, no Exclusivity rights covering the active ingredient contained in Venofer® are in force anywhere in the world (including in the US).

CONTACT

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Maltofer:

We, Vifor (International) Inc., herewith confirm that Maltofer[®] is the originator product and the first approved drug containing 'iron polymaltose' as an active ingredient. It was first authorized in Peru in February 1964 (marketing authorization number N-3820).

We furthermore confirm that no Patent applications were ever filed to protect the 'iron polymaltose' contained in Maltofer[®]. Therefore, no Exclusivity rights covering the active ingredient contained in Maltofer[®] are in force anywhere in the world (including in the US).

Kind regards,

Vifor (International) Inc.



Jean-Marc Ligibel
Head of IP



Raun Kupiec
Head of Regulatory Affairs Centre of Excellence



Resolución de asignación de número de registro

Santiago,

13 ENE 2016

Tipo / Nro Solicitud: Patente de invención / 2003 - 002118

Fecha de solicitud: 20/10/2003

Título: UN COMPLEJO DE CARBOHIDRATO DE HIERRO (III) HIDROSOLUBLE QUE COMPRENDE PRODUCTOS DE OXIDACION DE MALTODEXTRINA, QUE POSEE UN CONTENIDO DE HIERRO DE 15 HASTA 40 % (P/P) Y UN PESO MOLECULAR DE 100 KDA HASTA 300 KDA, DETERMINADO MEDIANTE CROMATOGRAFIA DE PERMEACION EN GEL.

Titular: VIFOR (INTERNATIONAL) AG.
Representante: HARNECKER.

Acreditado el pago de los derechos finales, asígnese el siguiente número de registro: 51553.

Resolución notificada por el Estado Diario con esta fecha.

CCP