

Santiago 26 de Diciembre de 2016

Estimado Cliente:

Junto con saludarlo, comunico a usted, de acuerdo a lo indicado por el fabricante: CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd., para los productos Inyectables detallados en anexo adjunto, el tapón de goma que contienen los frascos ampolla son fabricados con Bromobutilo y son **libres de látex**.

Esta información es entregada con el fin de respaldar la información técnica proporcionada por nuestro laboratorio.

Se despide atentamente de usted



Paulina Alegría M.
Director Técnico
OPKO Chile S.A.

OBS: SE ADJUNTAN CERTIFICADOS EMNITIDOS POR FABRICANTES



石药集团中诺药业（石家庄）有限公司

CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

To: OPKO Chile S.A.

From our consideration, all products included in the table N°1 are manufactured by our company under the GMP standards, and the packing materials used in them (such as the stoppers) is **free of Latex**.

Table N°1:

GENERIC NAME	REGISTERED NAME IN CHILE	MARKETING AUTHORIZATION NUMBER (IN CHILE)
BENZYL PENICILLIN SODIUM POWDER FOR INJECTION 1.000.000 IU	BENZYL PENICILLIN SODIUM POWDER FOR INJECTABLE SOLUTION 1.000.000 IU	F-14646
BENZATHINE BENZYL PENICILLIN POWDER FOR INJECTION 1.200.000 IU	BENZATHINE BENZYL PENICILLIN POWDER FOR INJECTABLE SUSPENSION 1.200.000 IU	F-14644
BENZYL PENICILLIN SODIUM POWDER FOR INJECTION 2.000.000 IU	BENZYL PENICILLIN SODIUM POWDER FOR INJECTABLE SOLUTION 2.000.000 IU	F-14647
CLOXACILLIN POWDER FOR INJECTION 500 mg	CLOXACILLIN SODIUM POWDER FOR INJECTABLE SOLUTION 500 mg	F-15263
CEFAZOLIN POWDER FOR INJECTION 1 g	ZELASTER POWDER FOR INJECTABLE SOLUTION 1 g	F-14840
CEFOTAXIME POWDER FOR INJECTION 1 g	ZEFTIMA POWDER FOR INJECTABLE SOLUTION 1 g	F-14841
CEFTAZIDIME POWDER FOR INJECTION 1 g	EFADIMA POWDER FOR INJECTABLE SOLUTION 1 g	F-14818
CEFTRIAXONE POWDER FOR INJECTION 1 g	CEFTAMOP POWDER FOR INJECTABLE SOLUTION 1 g	F-14925

This information is provided in order to give technical support to our client OPKO Chile S.A.

I hope this information will be useful for you

Attentively

石药集团中诺药业（石家庄）有限公司
CSPC ZHONGNUO PHARMACEUTICAL
(SHIJIAZHUANG) CO., LTD.

(Signature for Authority from CSPC Zhongnuo Pharm.)

声 明

Declaration

至：石药集团中诺药业（石家庄）有限公司

我公司为贵公司提供的注射用无菌粉末用卤化丁基橡胶塞（溴化）不含有乳胶成分。

特此声明！

To: CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

We, Hebei First Rubber Medical Technology Co., Ltd. hereby declare that the rubber stoppers for sterile powder for injections we manufactured are free of latex.

声明人：河北橡胶医药科技股份有限公司

二零一六年十二月十九日

Hebei First Rubber Medical Technology Co., Ltd.

Dec.19, 2016

声 明

Declaration

至：石药集团中诺药业（石家庄）有限公司

我公司为贵公司提供的注射用无菌粉末用卤化丁基橡胶塞（溴化）不含有乳胶成分。

特此声明！

To: CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

We, Jiangsu Best New Medical Material Co, Ltd., hereby declare that the rubber stoppers for sterile powder for injections we manufactured are free of latex.

声明人：江苏博生医用新材料股份有限公司

二零一六年十二月十九日

Jiangsu Best New Medical Material Co., Ltd.

Dec.19, 2016

声 明

Declaration

至：石药集团中诺药业（石家庄）有限公司

我公司为贵公司提供的注射用无菌粉末用卤化丁基橡胶塞（溴化）不含有乳胶成分。

特此声明！

To: CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

We, Yingcheng HengTian Pharmaceutical Package Co., Ltd., hereby declare that the rubber stoppers for sterile powder for injections we manufactured are free of latex.

声明人：应城市恒天药业包装有限公司

二零一六年十二月十九日

Yingcheng HengTian Pharmaceutical Package Co., Ltd.

Dec.19, 2016

声 明

Declaration

至：石药集团中诺药业（石家庄）有限公司

我公司为贵公司提供的注射用无菌粉末用卤化丁基橡胶塞（溴化）不含有乳胶成分。

特此声明！

To: CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

We, Zhengzhou Aoxiang Pharmaceutical Packing Co. Ltd., hereby declare that the rubber stoppers for sterile powder for injections we manufactured are free of latex.

声明人：郑州市翔翔医药科技股份有限公司

二零一六年十二月十九日

Zhengzhou Aoxiang Pharmaceutical Packing Co. Ltd.

Dec.19, 2016