



Spett.le
Astellas Pharma S.p.A.
Via delle Industrie, 1
20061 Carugate (MI)

OGGETTO: Assenza Lattice ASAMAX

"4g sospensione rettale - 7 contenitori monodose " A.I.C.: 034298048
"2g sospensione rettale - 7 contenitori monodose " A.I.C.: 034298036
"500 mg - 20 supposte " A.I.C.: 034298051

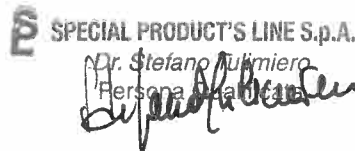
Il sottoscritto Dr. Stefano Tulimiero, (C.F.: TLMSFN42R08A509D), in qualità di Persona Qualificata dell'Officina Farmaceutica Special Product's Line S.p.A., sita in Via Campobello, 15 - 00040 Pomezia (Roma), autorizzata alla produzione del medicinale sopra in oggetto,

DICHIARA

che il medicinale **ASAMAX** nei dosaggi, forme farmaceutiche, confezioni e numeri A.I.C. riportati in oggetto, non contiene **LATTICE** sia nei materiali di confezionamento primario, sia negli elementi che compongono la forma farmaceutica.

In fede

Pomezia, 2 settembre 2010


SPECIAL PRODUCT'S LINE S.p.A.
Dr. Stefano Tulimiero
Persona Qualificata



STATEMENT

To whom it may concern

On the basis of the statements from our suppliers, we confirm that all the raw materials and packaging materials used in the manufacturing process of the medicinal product:

KCL RETARD TABLETS

Does not contain latex and gluten.

L'Aigle,
June 16, 2014

Sophie VECHEMBRE
Qualified Person

Siège Social : FAMAR L'AIGLE - ZI n°1 Secteur Ouest - Route de Crulai - B.P. 99 - F - 61303 L'AIGLE Cedex
Tél : +33(0)2 33 84 34 00 - Fax : +33(0)2 33 84 35 35
S.A.S au capital de 9.337.500 EUR - APE : 244C - Identification TVA : FR68 410 310 148 - Internet : www.famar.gr

FAMAR L'AIGLE Usine L'Aigle
ZI n°1 Secteur Ouest - Route de Crulai
B.P. 99 - F - 61303 L'AIGLE Cedex
Tél : +33(0)2 33 84 34 00 - Fax : +33(0)2 33 84 35 35
Siret: 410 310 148 00029

FAMAR L'AIGLE Usine St Rémy
Rue de l'Isle
B.P.103 - F - 28380 Saint Rémy sur Avre
Tél : +33(0)2 37 38 86 02 - Fax : +33(0)2 37 48 91 29
Siret: 410 310 148

Astellas Pharma Europe B.V.
Quality Management
Manufacturing Meppel
P.O. box 43
7940 AA Meppel
the Netherlands
Tel :+31 522 235300
Fax :+31 522 262881

Meppel, 9 September 2008

Concerns: Natural Latex Statement

LATEX STATEMENT

Omnic 0.4 mg Capsules

The above mentioned product of Astellas Pharma Europe B.V. is not tested with respect to natural latex.

As to the actual knowledge of our production process, raw materials and equipment used, we do not expect any natural latex and have no indication for any natural latex contained in the product.

On behalf of Astellas Pharma Europe B.V.



Drs. S. Griep
Manager Quality services
Qualified person