

**UCB PHARMA S.A.**

Chemin du Foriest  
B-1420 Braine-L'Alleud  
Belgium

Page 1 of 2

**Invoice n. 90000178**  
Document date: 08 January 2019

GLAXOSMITHKLINE CHILE FARMACÉUTICA LTDA.  
MÓDULO 1, NAVE PARQUE 14, ENEA PONIENTE  
AVENIDA BOULEVARD PONIENTE 1313  
8395 PUDAHUEL  
CHILI

**Bill-to address :**  
GLAXOSMITHKLINE TRADING SERVICES LTD  
980 GREAT WEST ROAD  
BRENTFORD  
Middlesex  
TW8 9GS  
GRANDE BRETAGNE

**Sold-to address :**  
GLAXOSMITHKLINE TRADING SERVICES LTD  
980 GREAT WEST ROAD  
BRENTFORD  
Middlesex  
TW8 9GS  
GRANDE BRETAGNE

VAT registration no: BE0810940487  
Payer: 20000391  
Your reference: BEBRA00003420904  
Our reference: 93209634  
Order date: 21 Sep 2018  
Terms of delivery: EXW BRAINE L'ALLEUD  
Mode of transport: Boat - Collected

Packaging Information  
Number of pieces  
2 Pallet

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Total number of units: 2 Piece

Currency: EUR

Invoice Details Material Code	Description	Batch Value	Quantity	Amount
CIA03203	KEPPRA IV 500MG/5ML 10VIA RB GSK CL	18054	1.895 EA	
	Gross Value	16,14 EUR / 1 EA		30.585,30
CIA03203	KEPPRA IV 500MG/5ML 10VIA RB GSK CL	18055	87 EA	
	Gross Value	16,14 EUR / 1 EA		1.404,18
Total Gross Value				31.989,48
Total item discount amount				0,00
Total Net Value				31.989,48
		<b>VAT%</b>	<b>VAT base</b>	<b>VAT</b>
Output Tax		21,00%	31.989,48 EUR	6.717,79

**To be paid (VAT incl.)** **38.707,27**

THIRTY-EIGHT THOUSAND SEVEN HUNDRED SEVEN EURO TWENTY-SEVEN

**Payment conditions:** Payment within 60 days due net  
**Latest due date:** 09 Mar 2019

**Shipping remarks:**

RPR / RPM : Brussels  
VAT/TVA/BTW : BE 0403.096.168  
Headquarters : Allée de la Recherche, 60  
B-1070 Brussels - Belgium

Phone: +41269190205  
Fax: +41269190245  
E-mail: frederique.derrien@ucb.com

BNP PARIBAS FORTIS S.A.  
SWIFT: GEBABEBB  
IBAN: BE46 2100 0459 6236

**UCB PHARMA S.A.**

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Belgium

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**Invoice n. 90000178**  
Document date: 08 January 2019

Material Code	Description	Batch Value	Quantity Price Unit	Amount Discount
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Order n°.: 1735097

Delivery n°.: 82278491

We hereby certify that this invoice is true and correct in all respects.

RPR / RPM : Brussels  
VAT/TVA/BTW : BE 0403.096.168  
Headquarters : Allée de la Recherche, 60  
B-1070 Brussels - Belgium

Phone: +41269190205  
Fax: +41269190245  
E-mail: frederique.derrien@ucb.com

BNP PARIBAS FORTIS S.A.  
SWIFT: GEBABEBB  
IBAN: BE46 2100 0459 6236



UCB s.a. Chemin du Foriest Bâtiment B4 CD- B 1420 Braine l'Alleud - TVA BE0403.096.168

**SHIPPING INSTRUCTIONS**  
**Camion en température dirigée 15->25°C**

**Transporteur**

Enlèvement fait par GSK

**Adresse de chargement**

UCB Pharma SA  
Chemin du Foriest  
Bâtiment B4 CD  
B - 1420 Braine l'Alleud  
Tel magasin : (02) 386.38.90  
Tel bureau (Di Raimondo / Desmedt (02) 386.36.26 ou 31.06

Notre Réf. 82278491

Braine l'Alleud le 02/01/2019

Messieurs,

Nous vous prions d'expédier par Mer les marchandises suivantes aux conditions reprises ci-dessous :

**Destinataire :**

Glaxosmithkline Chili Farmaceutica  
Modulo A - 6  
Avda Lo Boza  
8395 Pudahuel  
Chile

**Notify :**

**Document(s) pour le dédouanement et/ou destinataire :**

Facture : néant Colisage : 1 x Eur 1 : néant Certificat qualité : 1	<u>Valeur déclarée pour la douane :</u> € <u>Nombre et nature des colis :</u> 2 palettes superposables  <u>Poids net :</u> 384,508 kg <u>poids brut :</u> 424,508 kg <u>Nature de la marchandise :</u> Médicaments <u>Taric :</u> <input checked="" type="checkbox"/> 3004 9019 <input type="checkbox"/> 29337900 <u>Mode de paiement :</u> EXW Braine l'Alleud <u>Lettre de crédit :</u> <input type="checkbox"/>
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**Instructions spéciales pour le transporteur :**

**Transport en camion température dirigée entre 15 et 25°C**

de cool box : ☐

d' Envirotainer : ☐

NA : ☒

**PAS DE FACTURE AU CLIENT**

Le transport doit être réalisé en respectant les GDP (Good Distribution Practice), référence Guidelines on Good Distribution Practice of Medicinal Products for Human use (94/C 63/03).

**Instructions spéciales pour le Magasin :**

Nous comptons sur vos bons soins et vous prions d'agréer, Messieurs, nos salutations les meilleures.

Isabelle



**UCB PHARMA S.A.**

Chemin du Foriest  
B-1420 Braine-L'Alleud  
Belgium

Page 1 of 2

**Condensed Packing List 82278491**

Document date: 26 December 2018

## Ship-to address

GLAXOSMITHKLINE CHILE FARMACÉUTICA LTDA.  
MÓDULO 1, NAVE PARQUE 14, ENEA PONIENTE  
AVENIDA BOULEVARD PONIENTE 1313  
8395 PUDAHUEL  
CHILI

## Sold-to address:

GLAXOSMITHKLINE TRADING SERVICES LTD  
980 GREAT WEST ROAD  
BRENTFORD  
Middlesex  
TW8 9GS  
UNITED KINGDOM

## Shipping point address

Magasin B4  
Avenue de l'Industrie  
1420 Braine l'alleud  
Belgium

Req. delivery date: 10 Jan 2019  
Customer number: U013030  
Customer purch. Order: BEBRA00003420904  
Order number/date: 1735097 / 21 Sep 2018  
Customer VAT: GB239820839

Terms of delivery: EXW BRAINE L'ALLEUD

Means of transport: Boat - Collected

Packages: Pallet: 2

Loading weight:	384,508 KG	Gross HU:	424,508 KG	Total volume:	685,082 CD3
Net weight material:	384,508 KG	Gross material:	384,508 KG		

## E-GDP Information:

The product should be stored and transported according to its "Registered Storage Conditions".

The Storage Conditions on the shipping label reflect the "Warehouse temperature conditions" at which the products are stored at UCB. The warehouse temperature conditions will always be within the limits of the Registered Storage conditions.

For distribution activities, it is also acceptable to transport the product at the "Transport Conditions". Please note that those "Transport Conditions" may be broader than the "Registered Storage Conditions" only if they are supported by a set of scientific data approved by the quality unit."

## Shipping details

SSCC (HU Identification) Material	Description Batch Vendor Batch	Dimension Description	Loading weight Net weight Expiration date	Gross weight Qty material
154137870024200525	Pallet	80 x 120 x 110 CM	190,508	210,508 KG
CIA03203	18054	KEPPRA IV 500MG/5ML 10VIA RB GSK CL	173,630KG	895 EA
	18054		09 May 2021	
CIA03203	18055	KEPPRA IV 500MG/5ML 10VIA RB GSK CL	16,878KG	87 EA
	18055		10 May 2021	
180325296909816544	Pallet	80 x 120 CM	194	214 KG
CIA03203	18054	KEPPRA IV 500MG/5ML 10VIA RB GSK CL	194KG	1.000 EA
	18054		09 May 2021	



## UCB PHARMA S.A.

Chemin du Foriest  
B-1420 Braine-L'Alleud  
Belgium

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### Condensed Packing List 82278491

Document date: 26 December 2018

#### GDP Condition Details:

<b>Material</b>	: CIA03203 KEPBRA IV 500MG/5ML 10VIA RB GSK CL
<b>Warehouse temperature conditions</b>	: 15-25 °C (59-77°F)
<b>Other Storage Conditions</b>	: Not specified
<b>Registered Storage Conditions</b>	: Store below 25°C

**CERTIFICATE OF QUALITY**

ARTICLE CODE: **CIA03203**  
 TRADE NAME: **KEPPRA IV**  
 DOSAGE FORM: **Injectable Solution**  
 STRENGTH: **500mg/5ml**  
 PACKAGING SIZE: **5 ml**

complies with the required specifications as shown hereafter:

**CERTIFICATE OF ANALYSIS**

N° 201803780

BATCH: 18055


**SPECIFICATIONS**
**PARAMETERS**
**SPECIFICATIONS**
**RESULTS**

PARAMETERS	SPECIFICATIONS	RESULTS
Description	Clear and colourless solution, free from visible particulate matter	Complies
Identification of Levetiracetam (Achiral HPLC)	Positive	Positive
Identification of Levetiracetam (Chiral HPLC)	Positive	Positive
Assay of Levetiracetam	95.0 % - 105.0 %	99.7 %
<b>Achiral related substances</b>		
- ucb L057	Not more than 0.20 %	< LOQ
- Any related substance	Not more than 0.10 %	n.d.
- Total of achiral related substances	Not more than 0.80 %	< LOQ
<b>Chiral related substance</b>		
- ucb L060	Not more than 0.80 %	0.32 %
pH	5.5 +/- 0.5	5.5
Particulate contamination: sub-visible particles	For particles >= 10 µm, not more than 6000 per container	12 particles >= 10 µm
Particulate contamination: sub-visible particles	For particles >= 25 µm, not more than 600 per container	0 particles >= 25 µm
Extractable volume	Not less than 5.0 ml	5.2 ml
Sterility	Sterile	Sterile
Bacterial endotoxins	Not more than 3.7 IU/ml	< 2.7 IU/ml

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries

Quantity: 87 U      Registered Storage conditions : Store below 25°C  
 Manufacturing date: 11/05/2018      Expiry date : 10/05/2021  
 Country: CHILE

<input checked="" type="checkbox"/>	No deviation occurred during the manufacturing and / or testing and /or packaging of this batch
<input type="checkbox"/>	The deviation listed below has been investigated and approved by the Quality Assurance department

Qualified Person <input type="checkbox"/> Dr. P. Pizzorni <input checked="" type="checkbox"/> Dr. M. G. Valle	Signature 
---	--

30 November 2018

## ADDENDUM TO RELEASE CERTIFICATE

### PACKAGING COMPONENTS

Drug Product: Keppra IV 500 mg / 5 ml injectable solution  
Batch n. 18055  
Country: CHILE  
Cod.: CIA03203

The following Packaging Materials have been used for the packaging of the Drug Product described above:

- Label	CIA78570/C
- Leaflet	CIA78569/E
- Carton	CIA78568/C

We certify that they are fully in compliance with the approved UCB Master Packaging, with the cGMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Qualified Person	Signature
<input type="checkbox"/> Dr P. Pizzorni	
<input checked="" type="checkbox"/> Dr M. G. Valle	







**AESICA**  
A Consort Medical Company

30 November 2018

**CERTIFICATE OF QUALITY**

ARTICLE CODE: **CIA03203**  
TRADE NAME: **KEPPRA IV**  
DOSAGE FORM: **Injectable Solution**  
STRENGTH: **500mg/5ml**  
PACKAGING SIZE: **5 ml**

complies with the required specifications as shown hereafter:

**CERTIFICATE OF ANALYSIS**

N° 201803761

BATCH: 18054

**SPECIFICATIONS**

**PARAMETERS**

**SPECIFICATIONS**

**RESULTS**

Description	Clear and colourless solution, free from visible particulate matter	Complies
Identification of Levetiracetam (Achiral HPLC)	Positive	Positive
Identification of Levetiracetam (Chiral HPLC)	Positive	Positive
Assay of Levetiracetam	95.0 % - 105.0 %	100.3 %
<b>Achiral related substances</b>		
- ucb L057	Not more than 0.20 %	< LOD
- Any related substance	Not more than 0.10 %	n.d.
- Total of achiral related substances	Not more than 0.80 %	< LOQ
<b>Chiral related substance</b>		
- ucb L060	Not more than 0.80 %	0.32 %
pH	5.5 +/- 0.5	5.5
Particulate contamination: sub-visible particles	For particles >= 10 µm, not more than 6000 per container	11 particles >= 10 µm
Particulate contamination: sub-visible particles	For particles >= 25 µm, not more than 600 per container	0 particles >= 25 µm
Extractable volume	Not less than 5.0 ml	5.2 ml
Sterility	Sterile	Sterile
Bacterial endotoxins	Not more than 3.7 IU/ml	< 2.7 IU/ml

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries

Quantity: 1,895 U Registered Storage conditions: Store below 25°C  
Manufacturing date: 10/05/2018 Expiry date: 09/05/2021  
Country: CHILE

<input checked="" type="checkbox"/>	No deviation occurred during the manufacturing and / or testing and / or packaging of this batch
<input type="checkbox"/>	The deviation listed below has been investigated and approved by the Quality Assurance department
Qualified Person	Signature
<input type="checkbox"/> Dr. P. Pizzorni	
<input checked="" type="checkbox"/> Dr. M. G. Valle	

Aesica Pharmaceuticals S.r.l.  
Sede legale: Via Praglia, 15  
10044 Pianezza (TO)  
Italia

T: +39 011 96601  
F: +39 011 9660244  
E: enquiries@aesica-pharma.com  
www.aesica-pharma.com

Capitale Sociale: Euro 10.000,00 Registro delle Imprese di  
Torino n° iscrizione REATO-1133689, C.F. e P. IVA 07235480969  
Società soggetta a direzione e coordinamento da parte di Consort  
Medical S.r.l., Sede legale in Via Praglia n. 15, Pianezza (TO) - Italia  
Aesica is a trademark of Aesica Pharmaceuticals Limited

30 November 2018

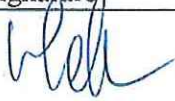
**ADDENDUM TO RELEASE CERTIFICATE**  
**PACKAGING COMPONENTS**

Drug Product: Keppra IV 500 mg / 5 ml injectable solution  
Batch n. 18054  
Country: CHILE  
Cod.: CIA03203

The following Packaging Materials have been used for the packaging of the Drug Product described above:

- Label	CIA78570/C
- Leaflet	CIA78569/E
- Carton	CIA78568/C

We certify that they are fully in compliance with the approved UCB Master Packaging, with the cGMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Qualified Person	Signature
<input type="checkbox"/> Dr P. Pizzorni <input checked="" type="checkbox"/> Dr M. G. Valle	



**UCB PHARMA S.A.**

Chemin du Foriest  
B-1420 Braine-L'Alleud  
Belgium

**Proforma : 93204807**

Document date: 02 January 2019

GLAXOSMITHKLINE CHILE FARMACÉUTICA LTDA.  
MÓDULO 1, NAVE PARQUE 14, ENEA PONIENTE  
AVENIDA BOULEVARD PONIENTE 1313  
8395 PUDAHUEL  
CHILI

**Bill-to address :**  
GLAXOSMITHKLINE TRADING SERVICES LTD  
980 GREAT WEST ROAD  
BRENTFORD  
Middlesex  
TW8 9GS  
GRANDE BRETAGNE

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GLAXOSMITHKLINE TRADING SERVICES LTD  
980 GREAT WEST ROAD  
BRENTFORD  
Middlesex  
TW8 9GS  
GRANDE BRETAGNE

VAT registration no: BE0810940487  
Payer: 20000391  
Your reference: BEBRA00003420904  
Our reference: 93204807  
Order date: 21 Sep 2018  
Terms of delivery: EXW BRAINE L'ALLEUD  
Mode of transport: Boat - Collected

Packaging Information  
Number of pieces  
2 Pallet

-----  
Total number of units: 2 Piece

Currency: EUR

Invoice Details Material Code	Description	Batch Value	Quantity	Amount
CIA03203	KEPPRA IV 500MG/5ML 10VIA RB GSK CL	18054	1.895 EA	
	Customs Value	16,14 EUR / 1 EA		30.585,30
CIA03203	KEPPRA IV 500MG/5ML 10VIA RB GSK CL	18055	87 EA	
	Customs Value	16,14 EUR / 1 EA		1.404,18
Total Customs Value				31.989,48
Total item discount amount				0,00
Total Net Value				31.989,48
		<b>VAT%</b>	<b>VAT base</b>	<b>VAT</b>
Output Tax		21,00%	31.989,48 EUR	6.717,79
<b>Total Value (VAT incl.):</b>				<b>38.707,27</b>

THIRTY-EIGHT THOUSAND SEVEN HUNDRED SEVEN EURO TWENTY-SEVEN

**Payment conditions:** Payment within 60 days due net  
**Latest due date:** 03 Mar 2019

**Shipping remarks:**

RPR / RPM : Brussels  
VAT/TVA/BTW : BE 0403.096.168  
Headquarters : Allée de la Recherche, 60  
B-1070 Brussels - Belgium

Phone: +41269190205  
Fax: +41269190245  
E-mail: frederique.derrien@ucb.com

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SWIFT: GEBABEBB  
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B-1420 Braine-L'Alleud  
Belgium

Page 2 of 2

**Proforma : 93204807**  
Document date: 02 January 2019

Material Code	Description	Batch Value	Quantity Price Unit	Amount Discount
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Order n°.: 1735097

Delivery n°.: 82278491

We hereby certify that this invoice is true and correct in all respects.

RPR / RPM : Brussels  
VAT/TVA/BTW : BE 0403.096.168  
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