



Agence nationale de sécurité du médicament
et des produits de santé

SPOR : PLM – PUI – UAT

- AMM
- AMMTRAD
- AMMVAR

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Chargé de l'appui aux process et outils AMM et EC
Date : 25/03/2024
SPOR

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-1- Premiers éléments de retour sur les tests PLM Portal



◆ **PLM PORTAL** : Production <https://plm-portal.ema.europa.eu/>

PLM PUI UAT montre une erreur en lien avec la section 3.17.1.8. Authorisation number: NAP in France of [Electronic submission of Article 57\(2\) data \(europa.eu\)](https://www.ema.europa.eu/en/documents/other/electronic-submission-article-572-data-questions-and-answers_en.pdf) :

https://www.ema.europa.eu/en/documents/other/electronic-submission-article-572-data-questions-and-answers_en.pdf

3.17.1.8. Authorisation number: NAP in France

Question: For medicinal products nationally authorised in France; a "package number" is stated in section 8 of the SmPC but it does not correspond to the Marketing Authorisation number (i.e. NL number) stated in the marketing authorisation document. Which number should be specified in the XEVPRM data element Authorisation number (AP.12.4) ?

Answer: If you wish to submit only one XEVMPD product entity for all the pack sizes covered by **the NL number**, you should specify the **NL number** in the data element Authorisation number (AP.12.4). If you wish to submit multiple XEVMPD product entities (i.e. one for each pack size), you may specify the **NL number** or the package number stated in section 8 of the SmPC in the data element AP.12.4. MAHs are not required to perform a dedicated update of their product entities in Article 57 database to amend this information; this can be done as part of a regular maintenance of the AMP entities.

◆ **La mesure corrective simple :**

- ▶ UTILISER LE **CIS** à la place à 8 chiffres et sans caractère espace (6nnnnnnn) pour « Authorisation number covering all pack sizes »
- ▶ UTILISER LE **CIP** dans le nouveau format 13 chiffres et sans caractère espace (34009nnnnnnnn) pour « Authorisation number at individual pack size level »

2 – RMP/DCP et NAT : données incomplètes ou confidentielles

 = données confidentielles

PMS ID

Full Name

Authorised Dose Form

MA Holder

MA Nr.

Active Substance





Authorisation Country

Authorisation Status


MRP / DCP / CP Nr.

Column visibility Download Load 10 rows


View Selected Products


<input type="checkbox"/>	↓ PMS ID	Full Name	Authorised Dose Form	MA Holder	MA Nr.	Active substance	Authorisation Country	Authorisation Status	MRP / DCP / CP Nr.
<input type="checkbox"/>	600000992665	TCAPS 25 microgrammes capsule molle	Capsule, soft	IBSA Pharma S.A.S.		Levothyroxine sodium	FR	Valid	
<input type="checkbox"/>	600000992691	FEMADIXIL 18,9 mg, ovule	Pessary	Laboratoires Majorelle		Benzalkonium chloride	FR	Valid	
<input type="checkbox"/>	600000995329	CEFTAZIDIME HOSPIRA 1 g, poudre pour solution injectable/pour perfusion (IM, IV)	Powder for solution for injection/infusion	Hospira France		Ceftazidime pentahydrate	FR	Withdrawn	UK/H/5611/003
<input type="checkbox"/>	600000994945	SILDENAFIL BGR 100 mg, comprimé pelliculé	Film-coated tablet	Biogaran		Sildenafil	FR	Valid	
<input type="checkbox"/>	600001000272	LINEZOLIDE STRAGEN 600 mg, comprimé pelliculé	Film-coated tablet	Stragen France		Linezolid	FR	Valid - Transferred marketing authorisation	AT/H/0491/001
<input type="checkbox"/>	600000995161	SPIRAMYCINE / METRONIDAZOLE CRISTERS 1,5 MUI / 250 mg, comprimé pelliculé	Film-coated tablet	Cristers		Metronidazole, Spiramycin	FR	Valid	
<input type="checkbox"/>	600000999297	OXYCODONE EG LP 30 mg, comprimé pelliculé à libération prolongée	Prolonged-release tablet	E G Labo Laboratoires Eurogenerics		Oxycodone	FR	Valid	DE/H/3641/005
<input type="checkbox"/>	600000994107	OVULASTEN 30, comprimé	Tablet	Chemical Farma	 3400949603695	Ethinylestradiol, Desogestrel	FR	Expired due to Sunset Clause	
<input type="checkbox"/>	600000996329	MIFLASON 400 microgrammes, poudre pour inhalation en gélule	Inhalation powder, hard capsule	Novartis Pharma S.A.S.		Beclometasone dipropionate	FR	Valid	
<input type="checkbox"/>	600000994114	Pramipexole Qualimed 0,088mg, comprimé	Tablet	Qualimed		Pramipexole	FR	Withdrawn	AT/H/0315/001

Show 1 to 10 of 10 entries Total Records: 21495


 **Your search returns 21495 Products.**
Please use filter criteria to narrow down the search results.

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3 – RMP/DCP et NAT – niveau Produit => CIS sans caractère espace (6nnnnnnn)



OVULASTEN 30, comprimé

PMS ID: 60000994107 | Authorisation Country: FR | MAH: ORG-100000394 | Authorisation Status: Expired due to Sunset Clause
Version Number: — | Last updated date: —

- Medicinal Product
- Marketing Authorisation Information**
- Therapeutic Indications
- Manufacturers
- Ingredients
- Medical Devices
- Manufactured Items
- Packaged Medicinal Product
- Marketing Authorisation Information
- Package Items
- Manufacturers
- Manufactured Items
- Medical Devices
- Pharmaceutical Product

Marketing Authorisation Information

Regulatory authorisation type	Marketing Authorisation	Date of first authorisation	—
Marketing authorisation number	3400949603695 67657252	International birth date	—
Country	French Republic	Marketing authorisation holder	Chemical Farma
Authorisation status	Expired due to Sunset Clause	Regulator	National Agency For The Safety Of Medicine Ar
Authorisation status date	11/10/2013	Procedure start date	—
MRP / DCP / CP Nr.	—	Procedure end date	—
Procédure type	National Procedure		

Regulatory application

Close ^

Regulatory application identifier/number —
Regulatory application type —
Regulatory application end date —

Close

Refresh

Export to XML

3 – RMP/DCP et NAT – niveau Présentations => CIP sans caractère espace (34009nnnnnnnn)

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Home > Product(s) of my Organisation(s) > Packaged Medicinal Product > Marketing Authorisation Information

OVULASTEN 30, comprimé
 PMS ID: 600000994107 | Authorisation Country: FR | MAH: ORG-100000394 | Authorisation Status: Expired due to Sunset Clause
 Version Number: — | Last updated date: —

Medical Product **Marketing Authorisation Information**

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply
-3400949603695	—	—	—	—

Package description 21 COMPRIMÉS SOUS PLAQUETTES THERMOFORMÉES (PVC/ALUMINIUM), BOÎTE DE 1 Language —

Marketing Authorisation (Package level) Open all ▾
Close ▲

Regulatory authorisation type Marketing Authorisation **Marketing authorisation number (Package level)** -3400949603695

Authorisation status Expired due to Sunset Clause **Authorisation status date (Package level)** 11/10/2013

Country —

Marketing Status Open ▾

Close Refresh Export to XML

3 – RMP/DCP et NAT : données attendues

PMS ID

Column visibility ▼ Download 📄 Load 10 rows

View Selected Products Edit Data View Data

Full Name

<input type="checkbox"/>	↓ PMS ID	Full Name	Authorised Dose Form	MA Holder	MA Nr.	Active substance	Authorisation Country	Authorisation Status	MRP / DCP / CP Nr.
<input type="checkbox"/>	600000992665	TCAPS 25 microgrammes capsule molle	Capsule, soft	IBSA Pharma S.A.S.	61819007	Levothyroxine sodium	FR	Valid	
<input type="checkbox"/>	600000992691	FEMADEXIL 18,9 mg, ovule	Pessary	Laboratoires Majorelle	66407452	Benzalkonium chloride	FR	Valid	
<input type="checkbox"/>	600000995329	CEFTAZIDIME HOSPIRA 1 g, poudre pour solution injectable/pour perfusion (IM, IV)	Powder for solution for injection/infusion	Hospira France	66406770	Ceftazidime pentahydrate	FR	Withdrawn	UK/H/5611/003
<input type="checkbox"/>	600000994945	SILDENAFIL BGR 100 mg, comprimé pelliculé	Film-coated tablet	Biogaran	68088462	Sildenafil	FR	Valid	
<input type="checkbox"/>	600001000272	LINEZOLIDE STRAGEN 600 mg, comprimé pelliculé	Film-coated tablet	Stragen France	63513482	Linezolid	FR	Valid - Transferred marketing authorisation	AT/H/0491/001
<input type="checkbox"/>	600000995161	SPIRAMYCINE / METRONIDAZOLE CRISTERS 1,5 MUI / 250 mg, comprimé pelliculé	Film-coated tablet	Cristers	65311860	Metronidazole, Spiramycin	FR	Valid	
<input type="checkbox"/>	600000999297	OXYCODONE EG LP 30 mg, comprimé pelliculé à libération prolongée	Prolonged-release tablet	E G Labo Laboratoires Eurogenerics	68282830	Oxycodone	FR	Valid	DE/H/3641/005
<input type="checkbox"/>	600000994107	OVULASTEN 30, comprimé	Tablet	Chemical Farma	67657252	Ethinylestradiol, Desogestrel	FR	Expired due to Sunset Clause	
<input type="checkbox"/>	600000996329	MIFLASONE 400 microgrammes, poudre pour inhalation en gélule	Inhalation powder, hard capsule	Novartis Pharma S.A.S.	67608173	Beclometasone dipropionate	FR	Valid	
<input type="checkbox"/>	600000994114	Pramipexole Qualimed 0.088mg, comprimé	Tablet	Qualimed	69443336	Pramipexole	FR	Withdrawn	AT/H/0315/001

Reset Search

Active Substance

Authorisation Country

FR ✕

Authorisation Status

MRP / DCP / CP Nr.

Show 1 to 10 of 10 entries Total Records: 21495

📘 Your search returns 21495 Products. Please use filter criteria to narrow down the search results.

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4 – Informations en provenance de SIAMED mieux gérées



< Product(s) of my Organisation(s)

PMS ID

Full Name

Authorised Dose Form

MA Holder

MA Nr.

Active Substance

Authorisation Country

Authorisation Status

MRP / DCP / CP Nr.

Column visibility ▾ Download **B** Load 10 rows


View Selected Products

<input type="checkbox"/>	↓ PMS ID	Full Name	Authorised Dose Form	MA Holder	MA Nr.	Active substance	Authorisation Country	Authorisation Status	MRP / DCP / CP Nr.
<input type="checkbox"/>	600000252694	Insulin lispro Sanofi 100 U/ml - Solution for injection	Solution for injection		EU/1/17/1203		EU	Valid	EMEA/H /C/004303
<input type="checkbox"/>	600000252632	Cimzia 200 mg - Solution for injection	Solution for injection	UCB Pharma	EU/1/09/544	Certolizumab pegol	EU	Valid	EMEA/H /C/001037
<input type="checkbox"/>	600000252708	Cyltezo 40 mg solution for injection in pre-filled pen	Solution for injection	Boehringer Ingelheim International GmbH	EU/1/17/1240	Adalimumab	EU	Withdrawn	EMEA/H /C/004319
<input type="checkbox"/>	600000252797	Cosentyx 150 mg solution for injection in pre-filled pen	Solution for injection	Novartis Europharm Limited	EU/1/14/980	Secukinumab	EU	Valid	EMEA/H /C/003729
<input type="checkbox"/>	600000252648	Aranesp 50 micrograms solution for injection in pre-filled pen	Solution for injection	Amgen Europe B.V.	EU/1/01/185	Darbepoetin alfa	EU	Valid	EMEA/H /C/000332
<input type="checkbox"/>	600000252517	Liprolog 100 units/ml, solution for injection in cartridge	Solution for injection	Eli Lilly Nederland B.V.	EU/1/01/195	Insulin lispro	EU	Valid	EMEA/H /C/000393
<input type="checkbox"/>	600000252530	HBVAXPRO 10 micrograms, suspension for injection in pre-filled syringe; Hepatitis B vaccine (recombinant DNA)	Suspension for injection	Merck Sharp & Dohme B.V.	EU/1/01/183	HEPATITIS B SURFACE ANTIGEN (RDNA) ADSORBED ON AM...	EU	Valid	EMEA/H /C/000373

Aranesp 20
 Show 1 to 10 of 10 entries Total Records: 6400


Your search returns 6400 Products.
 Please use filter criteria to narrow down the search results.

4 – Informations en provenance de SIAMED mieux gérées

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**HBVAXPRO 10 micrograms, suspension for injection in pre-filled syringe; Hepatitis B vaccine (recombinant DNA)**
PMS ID: 600000252530 | Authorisation Country: EU | MAH: ORG-100000760 | Authorisation Status: Valid
Version Number: – | Last updated date: –

Medical Product **Marketing Authorisation Information**

Marketing Authorisation Information

Therapeutic Indications

Manufacturers

Ingredients

Medical Devices

Manufactured Items

Packaged Medicinal Product

Marketing Authorisation Information

Package Items


Manufacturers

Manufactured Items

Medical Devices

Pharmaceutical Product

Marketing Authorisation Information

Download 

MA number	Package size(s)	PCID	EV code	Legal status of supply
EU/1/01/183/009	1 pre-filled syringe with attached needle	–	–	Medicinal product subject to medical prescription
EU/1/01/183/010	10 pre-filled syringes with attached needle	–	–	Medicinal product subject to medical prescription
EU/1/01/183/011	–	–	–	Medicinal product subject to medical prescription
EU/1/01/183/012	3 pre-filled syringes without needle	–	–	Medicinal product subject to medical prescription
EU/1/01/183/013	–	–	–	Medicinal product subject to medical prescription
EU/1/01/183/014	20 pre-filled syringes without needle	–	–	Medicinal product subject to medical prescription
EU/1/01/183/026	–	–	–	Medicinal product subject to medical prescription
EU/1/01/183/027	–	–	–	Medicinal product subject to medical prescription
EU/1/01/183/028	–	–	–	Medicinal product subject to medical prescription
EU/1/01/183/029	–	–	–	Medicinal product subject to medical prescription

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