Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 109854 DIPHERELINE triptorelin {as embonate} 3.75mg powder for suspension vial and water for injections ampoule

ARTG entry for	Medicine Registered
Sponsor	Ipsen Pty Ltd
Postal Address	Level 2 Building 4 Brandon Office Park 540 Springvale Road, GLEN WAVERLEY, VIC, 3150 Australia
ARTG Start Date	28/08/2006
Product category	Medicine
Status	Active
Approval area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. DIPHERELINE triptorelin {as embonate} 3.75mg powder for suspension vial and water for injections ampoule

Product Type Composite Pack **Effective date** 2/08/2017

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Diphereline is indicated for the treatment of hormone-dependent locally advanced or metastatic prostate cancer.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size
1

Poison Schedule
(S4) Prescription Only Medicine

Components

1. water for injections ampoule

Dosage Form	Injection, diluent for
Route of Administration	Intramuscular
Visual Identification	

2. DIPHERELINE triptorelin {as embonate}3.75mg powder for suspension vial

Dosage Form	Injection, modified release
Route of Administration	Intramuscular
Visual Identification	white to slightly yellow powder

Active Ingredients

Public Summary

triptorelin embonate	**5.6 mg**

Public Summary

IPSEN PHARMA BIOTECH
GMP certificate N° : HPF / FR / 195 / 2016
Number of manufacturing authorisation : M13 / 216
Parc d'Activités du Plateau de Signes
Chemin Départemental n°402
83870 SIGNES
TEL : + 33 (0)4 94 10 76 76
FRANCE

Certificate of Analysis and Compliance

Certificat d'analyses et de Conformité

Version:1

Inspection lot / *Lot de contrôle* : 40000203987
IPSEN Lot Number / *N° de lot IPSEN* : N21392
Bulk Lot Number: N07309
Manufacturing Date / *Date de fabrication* : 14/MAY/2018
Expiry date / *Date expiration* : 30/APR/2021
Specification reference/ *Référence spécification* : 1000622-L
Procedure / *Procédure analytique* : 025006-SPC

Material code / *Code article* : 1000622
Article name / *Libellé article* : DIPHERELINE 3,75MG 1FLCN RO
Supplier batch n° / *N° de lot fournisseur* : N/A

Test / *Essai*	Method / *Méthode*	Specification / *Spécification*	Result / *Résultat*	Unit / *Unité*
CARACTERES / *CHARACTERISTICS*				
Caractères Généraux *General Characteristics*	N/A	Conforme *Passed*	Conforme *Passed*	. .
Test injection *Injection test*	N/A	Conforme *Passed*	Conforme *Passed*	. .
IDENTIFICATION / *IDENTIFICATION*				
Triptoréline Acétate par CLHP *Triptorelin Acetate by HPLC*	N/A	Conforme *Passed*	Conforme *Passed*	. .
Spectrophotométrie UV *UV Spectrophotometry*	N/A	Conforme *Passed*	Conforme *Passed*	. .
ESSAI / *TESTS*				
Pureté *Purity*	N/A	>=96	97.8	% *%*
Impuretés individuelles *Individual impurities*	N/A	<=0.5	0.32	% *%*
Teneur en eau *Water content*	N/A	<=2.5	0.7	mg/flacon *mg/vial*
Teneur en dichlorométhane résiduel *Residuel methylene chloride content*	N/A	<=5.0	1.4	mg/flacon *mg/vial*
Libération in vitro : 2,4 heure *2.4 hours*	N/A	<= 27	13	% *%*
Libération in vitro : 59 heures *59 hours*	N/A	38-80	70	% *%*
Libération in vitro : 115 heures *115 hours*	N/A	>= 80	93	% *%*
DOSAGE / *ASSAY*				
Teneur Moyenne en triptoréline acétate *Triptorelin acetate Mean content*	N/A	3.75-4.50	4.09	mg/flacon *mg/vial*
EFFICACITE DE LA RADIOSTERILISATION / *RADIOSTERILISATION EFFICACITY*				
Dose de radiostérilisation (25 - 40 kGy) *Radiostérilisation dose*	N/A	Conforme *Passed*	Conforme *Passed*	. .
ANALYSES MICROBIOLOGIQUES / *MICROBIOLOGICAL TESTS*				
Endotoxines bactériennes *Bacterial endotoxins*	N/A	< 175	<17.5	UI/flacon *IU/vial*

This certificate was compiled by a validated laboratory information system and comes from therefore without genuine signatures. The approval was done in the laboratory information system by means of traceable electronic signatures

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Certificate of Analysis and Compliance

Certificat d'analyses et de Conformité

Version:1

Inspection lot */ Lot de contrôle* : 40000203987

IPSEN Lot Number */ N° de lot IPSEN* : N21392

Bulk Lot Number: N07309

Manufacturing Date */ Date de fabrication* : 14/MAY/2018

Expiry date */ Date expiration* : 30/APR/2021

Specification reference*/ Référence spécification* : 1000622-L

Procedure */ Procédure analytique* : 025006-SPC

Material code */ Code article* : 1000622

Article name */ Libellé article* : DIPHERELINE 3,75MG 1FLCN RO

Supplier batch n° */ N° de lot fournisseur* : N/A

CERTIFICAT DE LIBERATION / CERTIFICAT DE CONFORMITE :
CERTIFICATE OF RELEASE / CERTIFICATE OF COMPLIANCE :

" Je, soussignée, Personne Qualifiée d'Ipsen Pharma Biotech, au sens de la Directive de la Commission Européenne 2001/83/CE, certifie que le lot de produit a été fabriqué et contrôlé conformément aux Bonnes Pratiques de Fabrication et au dossier d'enregistrement approuvé par les Autorités de Santé.
Les résultats des contrôles réalisés sur ce lot sont conformes aux spécifications décrites dans le dossier d'enregistrement et permettent donc sa libération.
Toutes les matières premières et les articles de conditionnement entrant dans la fabrication de ce lot sont conformes à leurs spécifications."

" I, the undersigned, Qualified Person for Ipsen Pharma Biotech, as defined in 2001/83/EC European Commission Directive, hereby certify that the product batch was manufactured and tested according to Good Manufacturing Practices and the registration file approved by Health Authorities.
The results of the controls carried out on this batch are in compliance with the specifications of the registration file and therefore authorize its release.
All the raw materials and packaging items used for the manufacture of this batch are in accordance with their specifications. "

Personne Qualifiée / Qualified Person.

Conclusion */Conclusion* : ACCEPTE /RELEASED

Electronic signature */Signatures électroniques*

Approved by */Approuvé par* : GOMBERT as PERSONNE QUALIFIÉE / QUALIFIED PERSON

Date */Date* : 26/OCT/2018 15:17:53 UTC

Issued_By*/Edité par* : Sophie Gombert

Date /Date : 26/OCT/2018 15:18:22 UTC

IPSEN PHARMA BIOTECH
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Certificate of Analysis and Compliance

Certificat d'analyses et de Conformité

Version:1

Inspection lot */ Lot de contrôle* : 10000196316

IPSEN Lot Number */ N° de lot IPSEN* : N05303

Material code */ Code article* : 1049323

Article name */ Libellé article* : PSF MANNITOL 0.8% AMP 2ML DIN SST
Galenic Form : N/A

Manufacturing Date */ Date de fabrication* : 23/FEB/2017

Expiry date */ Date expiration* : 23/FEB/2022

Supplier name */ Nom fournisseur* : CENEXI

Supplier batch n° */ N° de lot fournisseur* : F1001

Specification reference*/ Référence spécification* : 1049323-A

Procedure */ Procédure analytique* : 321535-SPC

Test */ Essai*	Method */ Méthode*	Specification */ Spécification*	Result */ Résultat*	Unit */ Unité*
CARACTERES */ CHARACTERISTICS*				
Coloration *Colour*	N/A	La solution est incolore.	Conforme *Passed*	. .
Limpidité *Clarity*	N/A	La solution est limpide.	Conforme *Passed*	. .
CARACTERES */ CHARACTERISTICS*				
Contamination particulaire (>= 10 µm) *Particulate contamination (>= 10 µm)*	N/A	<= 6000	8	Part./ampoule
Contamination particulaire (>= 25 µm) *Particulate contamination (>= 25 µm)*	N/A	<= 600	0	Part./ampoule
ESSAI */ TESTS*				
Volume extractible *Extractable volume*	N/A	>= 2.0	2.0	ml *ml*
pH *pH value*	N/A	5.5 à 7.5	6.5	. .
DOSAGE */ ASSAY*				
Dosage du Mannitol	N/A	0.76 à 0.84	0.79	%m/m *%w/w*
ANALYSES MICROBIOLOGIQUES */ MICROBIOLOGICAL TESTS*				
Stérilité *Sterility*	N/A	Conforme *Passed*	Conforme *Passed*	. .
Endotoxines bactériennes *Bacterial endotoxins*	N/A	< 0.25	<0.25	UI/ml *IU/ml*

This certificate was compiled by a validated laboratory information system and comes from therefore without genuine signatures. The approval was done in the laboratory information system by means of traceable electronic signatures

" Je, soussignée, Personne Qualifiée d'Ipsen Pharma Biotech, au sens de la Directive de la Commission Européenne 2001/83/CE, certifie que le lot de produit a été fabriqué et contrôlé conformément aux Bonnes Pratiques de Fabrication et au dossier d'enregistrement approuvé par les Autorités de Santé.
Les résultats des contrôles réalisés sur ce lot sont conformes aux spécifications décrites dans le dossier d'enregistrement et permettent donc sa libération.
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The results of the controls carried out on this batch are in compliance with the specifications of the registration file and therefore authorize its release.
All the raw materials and packaging items used for the manufacture of this batch are in accordance with their specifications. "

Conclusion */Conclusion* : Conforme

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Certificate of Analysis and Compliance

Certificat d'analyses et de Conformité

Version:1

Inspection lot */ Lot de contrôle* : 10000196316

IPSEN Lot Number */ N° de lot IPSEN* : N05303

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Expiry date */ Date expiration* : 23/FEB/2022

Specification reference*/ Référence spécification* : 1049323-A

Procedure */ Procédure analytique* : 321535-SPC

Material code */ Code article* : 1049323

Article name */ Libellé article* : PSF MANNITOL 0.8% AMP 2ML DIN SST
Galenic Form : N/A

Supplier name */ Nom fournisseur* : CENEXI

Supplier batch n° */ N° de lot fournisseur* : F1001

Electronic signature */Signatures électroniques*

Approved by */Approuvé par* : KERNEN as QUALITY MANAGER

Date */Date* : 07/MAR/2018 16:44:28 UTC

Issued_By*/Edité par* : Isabelle Seyler

Date /Date : 18/APR/2018 14:26:42 UTC

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***HPF/FR/195/2016***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:
The manufacturer: ***IPSEN PHARMA BIOTECH***
Site address: ***Parc d'Activités du Plateau de Signes, Chemin départemental N° 402, SIGNES, 83870, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M13/216*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. L.5124-3 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-04-22*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: hormones(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.2 Semi-solids Special Requirements 7 Other: hormones(en) 1.1.2.3 Small volume liquids Special Requirements 7 Other: hormones(en) 1.1.2.4 Solids and implants Special Requirements 7 Other: hormones(en)
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**

	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

Manufacture : The site is authorised to the parametric release of the only medicinal products whose marketing authorisation includes this operation. --- Signatory: Mrs Mélanie Cachet, head of pharmaceutical product inspection and counterfeiting fight department. --- The ANSM does not issue paper copies of good manufacturing practice certificates.

2016-08-24

Name and signature of the authorised person of the Competent Authority of France

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Confidential
French National Agency for Medicines and Health Products Safety
Tel: ***Confidential***
Fax: ***Confidential***