REPUBLIKA HRVATSKA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE

REPUBLIC OF CROATIA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
Ksaverska c. 4, 10000 ZAGREB, CROATIA
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OIB 37926884937

Klasa: UP/I-530-10/20-03/08
Ur.broj: 381-13-08/162-20-03

POTVRDA O PROVOĐENJU DOBRE PROIZVOĐAČKE PRAKSE[1,2]
CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1,2]

DIO 1
Part 1

Nakon provedenog nadzora u skladu sa člankom 111(5) Direktive 2001/83/EZ Europskog parlamenta i Vijeća.
Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

Nadležno tijelo Republike Hrvatske potvrđuje sljedeće:
The competent authority of Croatia confirms the following:

Proizvođač: **Vem Ilac Sanayi ve Ticaret A.S.**
The manufacturer: ***Vem Ilac Sanayi ve Ticaret A.S.***

Mjesto proizvodnje: **Çerkezköy Organize Sanayi Bölgesi Karaağaç Mah. Fatih Bulvari No:38 Kapaklı-TEKİRDAĞ 59510, Turska**
Site address: ***Çerkezköy Organize Sanayi Bölgesi Karaağaç Mah. Fatih Bulvari No:38 Kapaklı-TEKİRDAĞ 59510, Turkey***

Proveden je nadzor proizvođača izvan Europskog gospodarskog prostora, a koji se navodi u dokumentaciji odobrenja za stavljanje lijeka u promet, u skladu s člankom 111(4) Direktive 2001/83/EZ transponiranim u nacionalnom zakonodavstvu, članak 40. Zakona o lijekovima („Narodne novine“, broj 76/13., 90/14. i 100/18.).
Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation Art. 40 Medicinal Products Act (Official Gazette No. 76/13, 90/14 and 100/18).

Provedenim inspekcijskim nadzorom proizvođača, od kojih je posljednji proveden dana 14. listopada 2019. godine utvrđeno je da proizvođač udovoljava zahtjevima dobre proizvođačke prakse sukladno principima i smjernicama dobre proizvođačke prakse propisanim Direktivom 2003/94/EZ[3].

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 14/10/2019, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[3].

Ova potvrda odnosi se na stanje mjesta proizvodnje u trenutku provedbe gore navedenog nadzora, i ne treba se smatrati da odražava stvarno stanje usklađenosti ukoliko su prošle više od tri godine od datuma nadzora. Međutim, rok važenja potvrde može se skratiti ili produljiti na temelju principa primijenjenog upravljanja rizicima inspekcije Agencije, na način da se isto unese u polje Ograničenja i pojašnjenja.

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.

Ova potvrda vrijedi isključivo ukoliko sadrži sve stranice, kao i DIO 1 i dijela DIO 2.

DIO 2
Part 2

☒ **Lijekovi Human** ***Medicinal Products***	
1. PROIZVODNJA ***1. MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS***	
1.1.	**Sterilni lijekovi** ***Sterile products***
	1.1.1. Aseptički pripravljeni lijekovi *Aseptically prepared* 1.1.1.4. Tekućine malih volumena *Small volume liquids* 1.1.1.6. Ostali aseptički pripravljeni oblici: *Other aseptically prepared products:* Prašak za otopinu za injekciju ili infuziju *Powder for solution for injection or infusion*
1.5.	**Opremanje** ***Packaging***
	1.5.2. Vanjsko pakiranje *Secondary packing*
1.6.	**Provjera kakvoće** ***Quality control testing***
	1.6.1. Mikrobiološko ispitivanje: sterilnost *Microbiological: sterility*
	1.6.2. Mikrobiološko ispitivanje: mikrobiološka čistoća *Microbiological: non-sterility*
	1.6.3. Kemijska/fizička ispitivanja *Chemical/Physical*

Ograničenje ili pojašnjenje vezano za navedeno u ovoj potvrdi:
Any restrictions or clarifying remarks related to the scope of this certificate:

Opseg ove potvrde o provođenju dobre proizvođačke prakse se odnosi na proizvodnu liniju Ampoule-1 line i Sterile Powder Line.
Scope of this GMP certificate is refering to manufacturing lines Ampoule-1 line and Sterile Powder Line.

Datum: 20.04.2020.
Date: 20/04/2020

Ime, prezime i potpis ovlaštene osobe
nadležnog tijela Republike Hrvatske
Name and signature of the authorised person
of the Competent Authority of Croatia

Inspektor Agencije
Inspector

Saša Polović, MChem

Agencija za lijekove i medicinske proizvode
Agency for Medicinal Products and Medical Devices
of Croatia

Dragomir Budimir, LLM

REPUBLIKA HRVATSKA - AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE ZAGREB 2

This certificate is valid only when presented with all pages and both Parts 1 and 2.

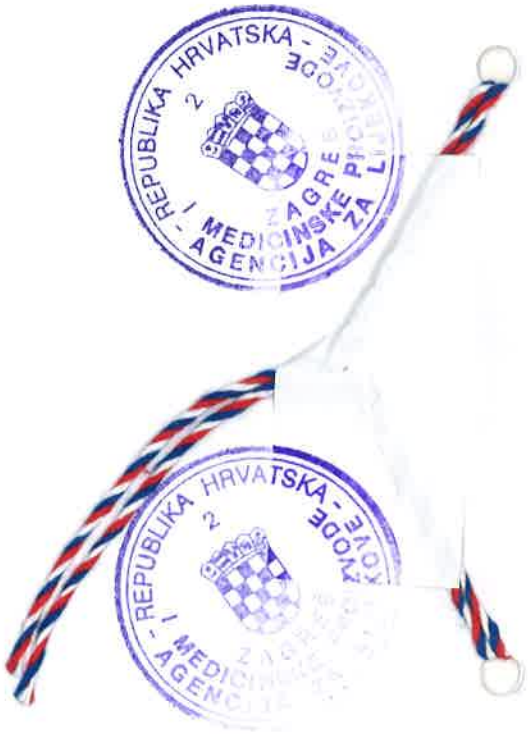
Autentičnost ove potvrde može se provjeriti u EudraGMDP bazi podataka. Ako nije dostupna u EudraGMDP bazi, obratite se tijelu koje je izdalo potvrdu.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

[1] GMP potvrda iz članka 111(5) Direktive 2001/83/EC primjenjuje se i za uvoznike.
The certificate referred to in paragraph 111(5) of Directive 2001/83/EC is also applicable to importers.

[2] Pojašnjenje ovog obrasca nalazi se u „Help menu" EudraGMDP baze
Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database

[3] Ovi zahtjevi ispunjavaju preporučene zahtjeve WHO za DPP
These requirements fulfil the GMP recommendations of WHO


REPUBLIKA HRVATSKA - AGENCIJA ZA LIJEKOVE
ZAGREB

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet

CERTIFICATE NUMBER: ***OGYÉI/66425-8/2020***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of Hungary confirms the following:
The manufacturer: ***Idol Ilac Dolum Sanayi ve Tikaret AS***
Site address: ***Davutpasa cad. Cebealibey sokak No. 20 Topkapi, Istanbul, 34020, Turkey***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-01-28***, it is considered that it complies with:

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

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

This GMP certificate is valid for Fluoresceine 100 mg/mL solution for injection for human use (manufactured in unit Idol 1, Filling Line V). Due to COVID-19 pandemic, it has been granted based on Distant Assessment. On-site inspection will be performed as soon as the restrictions are lifted.

2021-05-20

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

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Confidential
National Institute of Pharmacy and Nutrition
Tel:***Confidential***
Fax:***Confidential***

Danish Medicines Agency

CERTIFICATE NUMBER: ***DK H 00114519***

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 Denmark confirms the following:
The manufacturer: ***Mefar Ilac Sanayii A.S.***
Site address: ***Ramazanoglu MahallesiEnsar Caddesi 20, Pendik, 34906, Turkey***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011715*** / ***LOC-100018623***
DUNS Number: ***56-543-7154***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-06-02***, 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 Art. 111(5) of Directive 2001/83/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	
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

2022-09-02

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

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Confidential
Danish Medicines Agency
Tel:***Confidential***
Fax:***Confidential***

T.C. SAĞLIK BAKANLIĞI

TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

RUHSATNAME

06.07.2017 tarih ve 2017/486 sayılı bu ruhsatname **EPTİCARD 20MG/10ML İV ENJEKSİYONLUK ÇÖZELTİ İÇEREN FLAKON** isimli beşeri tıbbi ürün için **VEM İLAÇ SAN. VE TİC. ANONİM ŞİRKETİ** firması adına tahsis edilmiştir.

Eki : Sertifika
Ruhsatname ID : 2127089
İş bu ruhsatname eki sertifika ile geçerlidir

Dr. Hak[illegible] GÜRSÖZ
Kurum Başkanı

T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

Ruhsatname ID : 2127089

Revizyon Tarihi : 04.08.2022
Revizyon No : 1

Bu sertifika **06.07.2017** tarih ve **2017/486** sayılı Ruhsatname eki olarak **EPTİCARD 20MG/10ML İV ENJEKSİYONLUK ÇÖZELTİ İÇEREN FLAKON** isimli **İlaç** için düzenlenmiştir.

REÇETELİ / REÇETESİZ	:	REÇETELİ
REÇETE TÜRÜ	:	KISITLANMIŞ BEYAZ REÇETE
RUHSAT SAHİBİ	:	VEM İLAÇ SAN. VE TİC. ANONİM ŞİRKETİ
ETKİN MADDE ADI	:	EPTİFİBATİD
ÜRETİM YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
PRİMER AMBALAJLAMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
SEKONDER AMBALAJLAMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
SERİ KONTROL ANALİZ YERİ İÇEREN SERİ SERBEST BIRAKMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
RAF ÖMRÜ(AY)	:	24 AY
SAKLAMA SICAKLIĞI (^{0}C)	:	2-8 °C ARASINDA BUZDOLABINDA
AMBALAJ TANIMI	:	KUTUDA, GRİ RENKLİ BROMOBUTİL KAUÇUK TIPALI, AL KAPÜŞON VE KIRMIZI RENKLİ FLİP-OFF KAPAKLI 10ML'LİK TİP I RENKSİZ CAM FLAKON
AMBALAJ BOYUTU	:	1 ADET
RUHSAT HARCI	:	31.03.2017/173
ANALİZ HARCI	:	25.01.2017/23 17.03.2017/86899001116

Bilimsel inceleme sonuçları uygun bulunmuş olup ruhsatname geçerliliğini korumaktadır.

Dr. Asım HOCAOĞLU
Kurum Başkan Yardımcısı

T.C. MINISTRY OF HEALTH

TURKISH DRUG AND MEDICAL DEVICE INSTITUTION

LICENSE

This registration certificate dated **06.07.2017**and numbered **2017/486** is allocated for the human medicinal product called **"EPTICARD 20 mg/10 ml I.V solution for injection, vial"** on behalf of **VEM İLAÇ SANAYİ VE TİC. ANONİM ŞİRKETİ**

Appendix: Certificate
License ID: 2127089
This license is valid with its appendix certificate.

Dr. Hakkı GÜRSÖZ
Head of Institution

Date of Revision: 04.08.2022
Revision no: 1

T.C. MINISTRY OF HEALTH
Turkish Drug and Medical Device Institution

This certificate is prepared as an appendix to license dated **06.07.2017** and numbered **2017/486** for the **drug** called "**EPTICARD 20 mg/10 ml I.V solution for injection, vial".**

PRESCRIPTION/NON-PRESCRIPTION	:	PRESCRIPTION
TYPE OF PRESCRIPTION	:	LIMITED WHITE
MARKETING AUTHORIZATION HOLDER	:	VEM İLAÇ SAN. VE TİC. ANONİM ŞİRKETİ
NAME OF ACTIVE SUBSTANCE	:	EPTIFIBATIDE
MANUFACTURING SITE	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
PRIMARY PACKAGING SITE	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
SECONDARY PACKAGING SITE	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
BATCH CONTROL ANALYSIS SITE	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
BATCH RELEASE SITE	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
SHELF LIFE (MONTH)	:	24 MONTHS
STORAGE TEMPERATURE (°C)	:	2-8°C IN REFRIGERATOR
DEFINITION OF PACKAGING	:	IN BOX, TYPE I COLORLESS, GLASS VIAL (10 ML) WITH GREY BROMOBUTYL RUBBER STOPPER, RED HOOD AND RED FLIP-OFF CAP
SIZE OF PACKAGING	:	1 VIAL
LICENSE CHARGE RECEIPT	:	31.03.2017/173
ANALYSIS CHARGE RECEIPT	:	25.01.2017/23 17.03.2017/86899001116

The results of scientific investigation has been found appropriate and the certificate is still valid.

Dr. Asım HOCAOĞLU
Vice-Chairman of Institution

T.C. SAĞLIK BAKANLIĞI

TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

RUHSATNAME

06.07.2017 tarih ve 2017/487 sayılı bu ruhsatname **EPTİCARD 75MG/100ML İV İNFÜZYON ÇÖZELTİSİ İÇEREN FLAKON** isimli beşeri tıbbi ürün için **VEM İLAÇ SAN. VE TİC. ANONİM ŞİRKETİ** firması adına tahsis edilmiştir.

Eki : Sertifika
Ruhsatname ID : 2127121
İş bu ruhsatname eki sertifika ile geçerlidir

Dr. Hakan GÜRSOZ
Kurum Başkanı

T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

Ruhsatname ID : 2127121

Revizyon Tarihi : 04.08.2022
Revizyon No : 1

Bu sertifika **06.07.2017** tarih ve **2017/487** sayılı Ruhsatname eki olarak **EPTİCARD 75MG/100ML İV İNFÜZYON ÇÖZELTİSİ İÇEREN FLAKON** isimli **İlaç** için düzenlenmiştir.

REÇETELİ / REÇETESİZ	:	REÇETELİ
REÇETE TÜRÜ	:	KISITLANMIŞ BEYAZ REÇETE
RUHSAT SAHİBİ	:	VEM İLAÇ SAN. VE TİC. ANONİM ŞİRKETİ
ETKİN MADDE ADI	:	EPTİFİBATİD
ÜRETİM YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
PRİMER AMBALAJLAMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
SEKONDER AMBALAJLAMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
SERİ KONTROL ANALİZ YERİ İÇEREN SERİ SERBEST BIRAKMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş. KAPAKLI/TEKİRDAĞ
RAF ÖMRÜ(AY)	:	24 AY
SAKLAMA SICAKLIĞI (^{0}C)	:	2-8 °C ARASINDA BUZDOLABINDA
AMBALAJ TANIMI	:	KUTUDA, GRİ RENKLİ BROMOBÜTİL KAUÇUK TIPALI, AL KAPÜŞON VE SARI RENKLİ FLİP-OFF KAPAKLI 100 ML'LİK RENKSİZ TİP I CAM FLAKON
AMBALAJ BOYUTU	:	1 ADET
RUHSAT HARCI	:	31.03.2017/174
ANALİZ HARCI	:	25.01.2017/22 17.03.2017/86897001112

Bilimsel inceleme sonuçları uygun bulunmuş olup ruhsatname geçerliliğini korumaktadır.

Dr. Asım HOCAOĞLU
Kurum Başkan Yardımcısı

T.C. MINISTRY OF HEALTH

TURKISH DRUG AND MEDICAL DEVICE INSTITUTION

LICENSE

This registration certificate dated **06.07.2017** and numbered **2017/487** is allocated for the human medicinal product called **"EPTICARD 75 mg/100 ml I.V. solution for injection, vial**" on behalf of VEM ILAC SAN. VE TIC. ANONIM SIRKETI.

Appendix: Certificate
Authorization ID: 2127121
This license is valid with its appendix certificate.

Dr. Hakki GURSOZ
Head of Institution

T.C. MINISTRY OF HEALTH
Turkish Drug and Medical Device Institution

Authorization ID: 2127121 Revision date: 04.08.2022
Revision no: 1

This certificate is prepared as an appendix to license dated **06.07.2017** and numbered **2017/487** for the **drug** called **"EPTICARD 75 mg/100 ml I.V. solution for injection, vial".**

PRESCRIPTION/NON-PRESCRIPTION:	PRESCRIPTION
TYPE OF PRESCRIPTION:	LIMITED WHITE
MARKETING AUTHORIZATION: HOLDER	VEM ILAC SAN. VE TIC. ANONIM SIRKETI
NAME OF ACTIVE SUBSTANCE:	EPTIFIBATIDE
LICENSOR / ORIGIN COMPANY:	VEM ILAC SAN. VE TIC. A.S. KAPAKLI/TEKIRDAG
MANUFACTURING SITE:	VEM ILAC SAN. VE TIC. A.S. KAPAKLI/TEKIRDAG
PRIMARY PACKAGING SITE:	VEM ILAC SAN. VE TIC. A.S. KAPAKLI/TEKIRDAG
SECONDARY PACKAGING SITE:	VEM ILAC SAN. VE TIC. A.S. KAPAKLI/TEKIRDAG
BATCH CONTROL ANALYSIS SITE:	VEM ILAC SAN. VE TIC. A.S.
BATCH RELEASE SITE	KAPAKLI/TEKIRDAG
SHELF LIFE (MONTH):	24 MOUNTHS
STORAGE TEMPERATURE (°C):	2-8°C IN REFRIGERATOR
DEFINITION OF PACKAGING:	IN BOX, TYPE I COLORLESS, GLASS VIAL (10 ML) WITH GREY BROMOBUTYL RUBBER STOPPER, RED HOOD AND RED FLIP-OFF CAP
SIZE OF PACKAGING:	1 VIAL
LICENSE CHARGE RECEIPT:	31.03.2017/174
ANALYSIS CHARGE RECEIPT:	25.01.2017/22 17.03.2017/86897001112

Results of the scientific examination are found to be appropriate and the license remains valid.

Dr. Asım HOCAOĞLU
Vice-Chairman of Agency

Cilt Sayısı: 238

Yaprak Sayısı: 90

YERLİ TIBBÎ MÜSTAHZARLAR RUHSATNAMESİ

Tahlil harcı makbuzunun Tarih Numarası
18.04.2011 / P2-2185
28.02.2011 / P2-1451

Ruhsat harcı makbuzunun Tarih Numarası
04.08.2011 / F00508

VEM İLAÇ SAN. VE TİC. LTD. ŞTİ.
MAZENİL 0.5mg/5ml IV ENJEKSİYONLUK ÇÖZELTİ İÇEREN AMPUL (Flumazenil)
tertip ettiği ismindeki
müstahzarın MEFAR İLAÇ SAN. A.Ş. Kurtköy-Pendik/İSTANBUL tarafından
İmali-Reçeteli satılmasına müsaade edilmiştir.

T.C. SAĞLIK BAKANLIĞI

Müstahzarın raf ömrü: 24 aydır. 28 Aralık 2011

(25 ^{0}C'nin altındaki oda sıcaklığında)

Ambalajı: Kutuda, tip I renksiz cam ampulde 5mlx5 adet.

28 Aralık 2011

Müstahzarın raf ömrü ...36...
ay ve saklama koşulu .....25.....
'C'nin altındaki oda sıcaklığıdır

28.05.13

İŞ BU RUHSATNAMEDE KAYITLI
PREPARATIN RUHSAT SAHİBİ
FİRMA ÜNVANININ
VEM İLAÇ SAN VE TİC A Ş
OLARAK DEĞİŞTİRİLMESİ UYGUN
BULUNMUŞTUR
11.01.2016

Bilimsel inceleme sonuçları uygun bulunmuş olup, ruhsatname geçerliliğini korumaktadır.
03.11.17

İş bu ruhsatnamede kayıtlı preparatın mevcut üretim,primer/ sekonder ambalajlama ve seri kontrol/analizini içeren seri serbest bırakma yerine alternatif olarak "Vem İlaç San. ve Tic.A.Ş.-Kapaklı/TEKİRDAĞ" eklenmiştir. 18.07.2017

İş bu ruhsatnamede kayıtlı preparatın mevcut onaylı bulk üretim, primer-sekonder ambalajlama, seri kontrol yeri içeren seri serbest bırakma yerlerinden "Mefar İlaç San. A.Ş.. Pendik/İSTANBUL" tesisinin çıkarılması uygundur. 12.7.18

№ 03066

19 ŞUB 2018

Volume number	Layer number
238	90

DOMESTIC MEDICAL PREPARATION LICENSE

Analysis charge receipt		License charge receipt	
Date	**Number**	**Date**	**Number**
18.04.2011	P2-2185	04/08/2011	/ F00508
28.02.2011	P2-1451		

It is allowed that the product formulated by VEM İLAÇ SAN. VE TİC. LTD. ŞTİ./ANKARA, manufactured by MEFAR İLAÇ SAN. A.Ş. Kurtköy-Pendik/İSTANBUL and called "MAZENİL 0.5 mg/5 ml I.V. Solution for Injection, Ampoule (Flumazenil)" can be sold as prescription drug by VEM İLAÇ SAN. VE TİC. LTD. ŞTİ / ANKARA.

Signed by Dr. Saim KERMAN

28 December 2011

Shelf life of drug product: 24 months. 28 December 2011
(At room temperature below 25ºC)

Packaging: In box, 5 ml x 5 type I colourless glass ampoules. 28 December 2011

Starting date of five-year scientific examination period is 28 December 2011 and it is confirmed

Shelf life of drug product: 36 months and storage condition is room temperature below 25°C. 28 May 2011

It was approved to change company title of registered product hereby with this license as “Vem İlaç San. ve Tic. A.Ş.” 11 January 2016

Results of the scientific examination results are confirmed and license remains valid. 03 November 2017

It was approved to add “Vem İlaç San. ve Tic. A.Ş./TEKİRDAĞ” as alternative to the current release site including manufacture, primary/secondary packaging and batch control/analysis of the product registered hereby with this certificate. 18 July 2017

It is suitable to remove “Mefar İlaç San. A.Ş., Pendik/İSTANBUL” from batch release sites including current approved bulk manufacturing, primary-secondary packaging, batch control site of the preparate registered in this certificate. 12 July 2019

SAĞLIK BAKANLIĞI

Cilt Sayısı : 248

Yaprak Sayısı : 18

YERLİ TIBBÎ MÜSTAHZARLAR RUHSATNAMESİ

Tahlil harcı makbuzunun		Ruhsat harcı makbuzunun	
Tarih	Numarası	Tarih	Numarası
21.02.2012 05.09.2012	F04193 F00223	25.01.2013	65

Vem İlaç San.ve Tic.Ltd.Şti.

tertip ettiği Milricor 10mg/10ml IV Enjeksiyon/İnfüzyon İçin Çözelti içeren Ampul (Milrinon) ismindeki

müstahzarın Mefar İlaç San.A.Ş.Pendik/İSTANBUL tarafından

İmali/Reçeteli satılmasına müsaade edilmiştir.

11 Şubat 2013

Dr. Hakkı Güpsöz
Kurum Eczacısı V.

SAĞLIK BAKANLIĞI

Müstahzarın raf ömrü 24 aydır.
(25 C'nin altındaki oda sıcaklığında)
İnfüzyonluk %0.45 ve %0.9 NaCl ve %5 lik Glukoz çözeltileri ile seyretildikten sonra 25 C'nin altındaki oda sıcaklığında 24 saat stabildir.

Ambalaj Tanımı: Kutuda, Tip I cam ampul,1 adet.

1 Şubat 2013

Beş yıllık bilimsel inceleme süresinin başlangıç tarihi 1 Şubat 2013 olup tasdik edilmiştir. 1 Şubat 2013

İş bu ruhsatnamede kayıtlı müstahzarın raf ömrü 25°C'nin altında oda sıcaklığında 48 aydır. 04.08.2016

AR Bilimsel inceleme sonuçları uygun bulunmuş olup, ruhsatname geçerliliğini korumaktadır. 6.6.18

İş bu ruhsatnamede kayıtlı preparatın mevcut üretim, primer/sekonder ambalajlama ve seri kontrol/analizini içeren seri serbest bırakma yerine alternatif olarak "Vem İlaç San. ve Tic.A.Ş. Kapaklı/TEKİRDAĞ" eklenmiştir. 16.07.2018

AC İş bu ruhsatnamede kayıtlı preparatın mecut onaylı bulk üretim, primer-sekonder ambalajlama, seri kontrol yeri içeren seri serbest bırakma yerlerinden "Mefar İlaç San. A.Ş., Pendik/İSTANBUL" tesisinin çıkarılması uygundur. 12.7.19

İş bu ruhsatnamede kayıtlı müstahzarın ruhsat sahibi ünvanının "Vem İlaç San.ve Tic.A.Ş."olarak değiştirilmesi uygun bulunmuştur.
18.08.2016

19 ŞUB 2018
№ 0306

Volume number	Layer number
248	18

DOMESTIC MEDICAL PREPARATION LICENSE

Analysis charge receipt		License charge receipt	
Date	**Number**	**Date**	**Number**
21.02.2012	F04193	25/01/2013	/ 65
05.09.2012	F00223		

It is allowed that the product formulated by VEM İLAÇ SAN. VE TİC. LTD. ŞTİ./ANKARA, manufactured by MEFAR İLAÇ SAN. A.Ş. Pendik/İSTANBUL and called "MILRICOR 10 mg/10 ml I.V. Solution for Injection/Infusion Ampoule (Milrinone)" can be sold as prescription drug by VEM İLAÇ SAN. VE TİC. LTD. ŞTİ / ANKARA.

Signed by Dr. Hakkı GÜRSÖZ
Vice President of Instutiton
(Seal and Signature)

11 February 2013

Shelf life of drug product is 24 months.
(At room temperature below 25ºC)
After it is diluted with %0.45 and 0.9 NaCl for infusion and %5 Glucose solutions, it is stable for 24 hours at room temperature below 25ºC. 11 February 2013 (Seal and Signature)

Packaging: In box, Type I glass ampoule, 1 unit. 11 February 2013 (Seal and Signature)

Starting date of five-year scientific examination period is 11 February 2013 and it is confirmed. (Seal and Signature)

Shelf life of drug product is 48 months and storage condition is room temperature below 25°C. 04 August 2016 (Seal and Signature)

It was approved to change company title of registered product hereby with this license as “Vem İlaç San. ve Tic. A.Ş.” 18 August 2016 (Seal and Signature)

Results of the scientific examination results are confirmed and license remains valid. 06 June 2018 (Seal and Signature)

It was approved to add “Vem İlaç San. ve Tic. A.Ş. Kapaklı/TEKİRDAĞ” as alternative to the current release site including manufacture, primary/secondary packaging and batch control/analysis of the product registered hereby with this certificate. 16 July 2018 (Seal and Signature)

It is suitable to remove “Mefar İlaç San. A.Ş., Pendik/İSTANBUL” from batch release sites including current approved bulk manufacturing, primary-secondary packaging, batch control site of the preparate registered in this certificate. 12 July 2019
(Seal and Signature)