

T.R. MINISTRY OF HEALTH
TURKISH AGENCY OF MEDICINE AND MEDICAL DEVICES
LICENSE

By this license with the date 22.04.2014 and number 2014/346, the product MOLTEK FDG IV ENJEKSİYONLUK ÇÖZELTİ İÇEREN FLAKON (MOLTEK FDG IV SOLUTION FOR INJECTION) is licensed to the company MOLTEK SAĞLIK HİZMETLERİ ÜRETİM VE PAZARLAMA A.Ş.

Appendix: Certificate

This license hereby is valid with its appendix-certificate.

(Signature and Seal)

Dr. Saim KERMAN

Agency Head

Tercüme Edilmek Üzere Bana Verilen
TÜRKÇE Dilindeki Belgeyi İNGİLİZCE
Diline Tam Ve Doğru Çevirdiğimi
Beyan Ederim.
Adnan Kahveci DOĞAN
Kadıköy/32. Noterliği
Yeminli Tercüman

T.R.

MINISTRY OF HEALTH

Turkish Agency of Medicine and Medical Devices

License ID: 12424

Revision Date: 27.01.2017

Revision No:1

This certificate is the appendix of the license with the date **22.04.2014** and number **2014/346**, issued for the medicine **MOLTEK FDG IV ENJEKSİYONLUK ÇÖZELTİ İÇEREN FLAKON (MOLTEK FDG IV SOLUTION FOR INJECTION)**.

PRESCRIPTION/NON-PRESCRIPTION	PRESCRIPTION
PRESCRIPTION TYPE	WHITE PRESCRIPTION
LICENSE HOLDER	MOLTEK SAĞLIK HİZMETLERİ ÜRETİM VE PAZARLAMA A.Ş.
ACTIVE SUSBTANCE NAME	FLUORODEOXYGLUCOSE (F18)
MANUFACTURING ADDRESS	MOLTEK MOLEKÜLER TEKNOLOJİ ARAŞ. SAN. VE TİC. A.Ş. GEBZE/KOCAELİ
PRIMARY PACKAGING SITE	MOLTEK MOLEKÜLER TEKNOLOJİ ARAŞ. SAN. VE TİC. A.Ş. GEBZE/KOCAELİ
SECONDARY PACKAGING SITE	MOLTEK MOLEKÜLER TEKNOLOJİ ARAŞ. SAN. VE TİC. A.Ş. GEBZE/KOCAELİ
BATCH RELEASE SITE INCLUDING THE BATCH CONTROL ANALYSIS SITE	MOLTEK MOLEKÜLER TEKNOLOJİ ARAŞ. SAN. VE TİC. A.Ş. GEBZE/KOCAELİ
SHELF LIFE	12 MONTHS
STORAGE TEMPERATURE (°C)	ROOM TEMPERATURE UNDER 25°C
PACKAGE DEFINITION	MULTIDOSE 10 ML COLORLESS TYPE I GLASS VIAL, CLOSED WITH GRAY BUTYL RUBBER LID AND ALUMINUM RING, INSIDE LEAD SHIELD ONE VIAL CONTAINS A MAXIMUM OF 10 ML SOLUTION, 1650 MBQ/ML ACTIVE SUBSTANCE AT THE CALIBRATION TIME
PACKAGE SIZE	1 VIAL
SCIENTIFIC EXAMINATION TIME FINISHED ON	25.09.2014
LICENSE FEE	17.04.2014/030600000055
ANALYSIS FEE	Undercover

(Signature)Ali ALKAN – Deputy to Assistant Agency Head

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