

12.03.2019 TARİHLİ TADALAFİL İÇEREN ÜRÜNLER_, ENG

RESTRICTED MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency of Turkey

NORMAL Number :62820468-000-E.41996 12.03.2019 Subject : Products Containing Tadalafil

DOSSIER

The sections on “Posology and mode of administration” in the Summary of Product Characteristics and Package Leaflet of the “Products Containing Tadalafil” need to be arranged as follows: For products containing 10 mg and 20 mg tadalafil: In general, the recommended dose is 10 mg to be taken at least 30 minutes prior to anticipated sexual activity. In those patients in whom tadalafil 10 mg does not produce an adequate effect, the dose may be increased to 20 mg. The maximum does frequency is once a day. Tadalafil’s 10 mg and 20 mg doses should be taken prior to anticipated sexual activity and continuous daily use is not recommended. It is not suitable for products containing 20 mg tadalafil (except for bisect tablets) to be taken after being split. For products containing 2.5-5 mg tadalafil: In general, the recommended dose is 10 mg to be taken at least 30 minutes prior to anticipated sexual activity. In those patients in whom tadalafil 10 mg does not produce an adequate effect, the dose may be increased to 20 mg. The maximum does frequency is once a day. Tadalafil’s 10 mg and 20 mg doses should be taken prior to anticipated sexual activity and continuous daily use is not recommended. In patients requiring more frequent use of tadalafil prior to intercourse (e.g. at least 2 times a week), the lowest daily dose may be considered depending on the preference of the patient and the judgment of the physician. Although the recommended dose in these patients is 5 mg once a day, the dose may be reduced to 2.5 mg once daily depending on individual tolerability. The adequacy of continuous use of the daily regimen should be re-evaluated on a periodic basis. In case of presence of “Benign prostate hyperplasia symptoms” and/or “Co-existence of benign prostate hyperplasia symptoms and erectile dysfunction” in the indications of the product: The recommended dose is 5 mg once a day taken at the same time every day. In patients who cannot tolerate 5 mg tadalafil use for benign prostate hyperplasia or in whom this dose is not effective, alternative treatment options should be considered. It is not suitable for products containing 5 mg tadalafil (except for bisect tablets) to be taken after being split. I hereby submit for your information and kindly request that SPC/PL applications on the products in which abovementioned changes are made are submitted to the Pharmacological Evaluation Unit until 28.03.2019. Dr. Hakkı GÜRSÖZ President of the Agency Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Turkish Pharmaceutical Industry Association Association of Innovator Pharmaceutical Companies Self-Care Products Association