



Prague, 2 April 2020

Ref. No.: MZDR 12756/2020-3/MIN/KAN



MZDRX019S378

EXTRAORDINARY MEASURE

The Ministry of Health, as the competent administrative authority pursuant to Section 80(1)(g) of Act No. 258/2000 Coll., on Public Health Protection and amendments to certain related acts, as amended (hereinafter referred to as “Act No. 258/2000 Coll.”), orders this extraordinary measure, proceeding pursuant to Section 69(1)(i) and (2) of Act No. 258/2000 Coll., in order to protect the population and prevent the occurrence and spread of the COVID-19 disease caused by the new SARS-CoV-2 coronavirus:

I.

1. **All physicians are prohibited from prescribing the medicinal product PLAQUENIL 200MG TBL FLM 60, registration number 25/209/00-C (hereinafter referred to as “PLAQUENIL”). This prohibition does not apply to:**
 - a) **physicians with special qualifications in the fields of allergology and clinical immunology, infectious medicine and rheumatology,**
 - b) **physicians with particular professional or particular specialised qualifications in the fields of child dermatovenerology, child rheumatology or corrective dermatology,**
 - c) **physicians with specialised qualifications in the fields of pneumology and phthisiology, when prescribing to patients already in treatment for sarcoidosis (D86),**
 - d) **physicians with particular professional or particular specialised qualifications in the fields of child pneumology and phthisiology, when prescribing to patients already in treatment for interstitial pulmonary diseases (J84),**
 - e) **prescriptions on the basis of request forms for use in the provision of in-patient care to patients with the COVID-19 disease.**
2. **All veterinarians are prohibited from prescribing the human pharmaceutical product PLAQUENIL.**
3. **All physicians with specialised qualifications in the fields of allergology and clinical immunology, dermatovenerology, infectious medicine or rheumatology, or with particular professional or particular specialised qualifications in the fields of child**

dermatovenerology, child rheumatology or corrective dermatology, are prohibited from prescribing the medicinal product PLAQUENIL for other therapeutic indications than those listed in the valid summary of product data. This prohibition does not apply to the prescribing of electronic prescriptions or hardcopy prescriptions by a physician with specialised qualifications in the fields of rheumatology or particular specialised qualifications in the fields of child rheumatology for patients already in treatment for Sjogren's syndrome with extra-glandular manifestations (M350), Non-differentiated or mixed connective tissue diseases (M358), Overlapping syndromes between connective tissue diseases (M351) or Dermatomyositis (M33).

4. All the physicians referred to in paragraphs 1 and 3 are prohibited from prescribing the medicinal product PLAQUENIL for treatment for more than 2 months or in more than 2 packages.
5. All physicians referred to in paragraphs 1 and 3 are ordered to always state the main diagnosis when prescribing the medicinal product PLAQUENIL.
6. All pharmacists are prohibited from
 - a) dispensing the medicinal product PLAQUENIL, if
 - i. the specialisation of the prescribing physician is not specified in the medical prescription,
 - ii. the main diagnosis linked to the prescribed medicinal product is not specified,
 - iii. the qualifications of the prescribing physician does not correspond to the specialisation referred to in articles 1 or 3, or
 - iv. it is prescribed for a different therapeutic indication than that specified in the valid summary of product data or in paragraphs 1 or 3,
 - b) to dispense more than 2 packages of the medicinal product PLAQUENIL.

This prohibition shall not apply to dispensing on the basis of request forms for use in the provision of in-patient care to patients with the COVID-19 disease.

II.

The medicinal product PLAQUENIL prescribed before 23 March 2020 by a physician referred to in paragraph 1(a) through (d) may be dispensed only during the validity of this medical prescription, unless it is a refill prescription, even if the main diagnosis is not specified in the medical prescription.

III.

This extraordinary measure takes effect on 3 April 2020.

IV

**This extraordinary measure cancels the extraordinary measure of the Ministry of Health
Ref. No. MZDR 12756/2020-2/MIN/KAN.**

Rationale:

This Extraordinary Measure has been issued in connection with the adverse development of the epidemiological situation in terms of the occurrence of the COVID-19 disease, caused by the novel coronavirus designated as SARS-CoV-2 in the Czech Republic.

According to available scientific findings, the medicinal product PLAQUENIL appears to be potentially effective in treating the COVID-19 disease. In connection to this information, there was an extreme rise in the prescription and dispensing of the medicinal product PLAQUENIL in the middle of March, and it was evident that this was unrelated to the ongoing treatment or potential treatment of patients hospitalised with the COVID-19 disease. Hence, the aim of the measure is to ensure that the medicinal product continues to be available for patients in treatment, while also ensuring the treatment of patients hospitalised with COVID-19 disease. The prescription of the medicinal product PLAQUENIL is therefore limited to physicians in the listed specialisations, who have used this product for treatment to date. This refers to the treatment of indications listed in the summary of product data, but also off-label indications for which scientific findings for use in treatment exist (although these indications are not listed in the summarised product data). However, the treatment of existing patients must be limited so as to prevent pre-stocking, which could cause an acute shortage of the medicinal product for treating COVID-19 patients; therefore, the period for which the medicinal product can be prescribed and the number of packages has been limited. The measure enables the use of the medicinal product PLAQUENIL for future patients with COVID-19 disease.

Mgr. et Mgr. Adam Vojtěch, MHA

Minister of Health

Signed electronically