

Medication Guide for Nemonoxacin-Containing Drugs

Please read this Medication Guide carefully before taking Taigexyn[®]. If you misplace this Medication Guide, you can download it from TaiGen Biotechnology company website at any time. If you have any questions regarding this drug, please consult your physician or pharmacist. If you experience any discomfort, please consult your physician as soon as possible for assessment and treatment. You can also report your condition to TaiGen Drug Safety Center via telephone or to the Taiwan National Adverse Drug Reaction Reporting Center. Relevant contact information is listed on the last page of this Medication Guide. This nemonoxacin-containing drug is prescribed by your physician for your personal use. Please not do give this drug to others, even if they have the same symptoms as you, since this may cause them harm.

Which patients should not take Taigexyn[®]?

- Patients with known allergies to any ingredient in this drug or other quinolones.
- Pregnant or breastfeeding women.
- Patients under 18 years of age.

Which patients are not recommended to take Taigexyn[®]?

- Patients with moderate to severe renal insufficiency and hepatic insufficiency.
- Patients with known prolonged QT interval.
- Taigexyn[®] is not recommended for use in patients with myasthenia gravis since quinolone use may worsen their condition.

Which patients should take extra precautions when taking Taigexyn[®]?

- Patients who must take concurrent medications that can prolong their QT interval should take extra precautions. Such drugs include erythromycin, antihistamines, antipsychotics, and tricyclic antidepressants, and Class Ia (e.g., quinidine or procainamide) or Class III (e.g., amiodarone or sotalol) antiarrhythmic agents. If you are unsure whether your current medication poses such risks, you should consult your physician.
- Patients with low blood potassium (hypokalemia) have a higher risk of a prolonged QT interval. Cooperation with your physician to receive treatment and correct to normal potassium levels is recommended.
- Although current safety information of Taigexyn[®] does not include case reports of neuropathy, tendon problems, or poor blood sugar control, previous data on quinolones have shown that elderly patients or patients concurrently taking steroids have a higher chance of tendon problems. Patients with diabetes may experience low blood sugar (hypoglycemia) and other forms of poor blood sugar control. Thus, patients with the above conditions should take extra precautions when taking Taigexyn[®].

Please take Taigexyn[®] at the dose prescribed by your physician.

- If you are unsure, please confirm with your physician or pharmacist.
- The recommended dose is two capsules (0.5 g) once a day. The length of treatment should be determined by your physician based on the severity of your symptoms or a clinical response. Taking Taigexyn[®] for 7 to 10 consecutive days is recommended, without skipping any dose or stopping the medication during the treatment period.

How should Taigexyn[®] be taken?

- Swallow whole capsules with water on an empty stomach.

- Take Taigexyn[®] at about the same time each day.
- Concurrently use of antacids or other formulations containing aluminum or magnesium should only be taken 2 hours after taking Taigexyn[®].
- Taking Taigexyn[®] simultaneously with ferrous formulations is not recommended.

If you forget to take Taigexyn[®]

- Take one dose as soon as you remember, but do not take more than one dose per day.
- The next dose should only be taken after at least 12 hours.

If you overdose on Taigexyn[®]

- If you overdose on Taigexyn[®] by accident, please contact your physician or pharmacist immediately.

Possible adverse reactions

- Like many other drugs, nemonoxacin-containing drugs may cause adverse reactions, but they do not necessarily occur in all patients.
- Based on the data from clinical trials, the most common (incidence greater than or equal to 1%) side effects include nausea, diarrhea, vomiting, abdominal discomfort, dizziness, elevated blood aminotransferase, lowered white blood cell counts (leukopenia), and elevated blood γ -glutamyl transferase.
- Adverse reactions reported for other quinolones include central nervous system problems such as seizures, tendon problems, skin phototoxicity, poor blood sugar control, serious allergic reactions, serious blister reactions, liver damage (hepatotoxicity), psychiatric reactions (development of suicidal thoughts and self-harm behaviors). At present, these adverse reactions have not been reported in clinical trials of Taigexyn[®], but precautions should still be taken.
- There have been reports of pseudomembranous colitis caused by broad-spectrum antibiotics. Thus, if severe diarrhea occurs during Taigexyn[®] treatment, this diagnosis should be considered.

Dealing with adverse reactions after taking Taigexyn[®]

- If you experience any discomfort or have any questions when taking Taigexyn[®], please contact and consult your physician, pharmacist, or relevant healthcare personnel who will perform detailed evaluation, data collection, and reporting of your drug safety information.
- If you have any questions, opinions, or experience any discomfort when taking Taigexyn[®], you can also provide your feedback and submit enquiries by calling or emailing the TaiGen Drug Safety Center. You can also report directly to the Taiwan National Adverse Drug Reaction Center.
- TaiGen will try to provide you with as much drug-related information as possible and will carefully record the relevant issues and information provided by you. We will compile the safety-related information provided by you for submission to the National Adverse Drug Reaction Center, in accordance with the provisions of Taiwanese regulations. We will also report periodically to the Taiwan Food and Drug Administration.

Contact Information

- This Medication Guide may be updated at any time, and the latest version is available for download on the TaiGen website.
- TaiGen website: <http://www.taigenbiotech.com.tw/>
- TaiGen Drug Safety Center 24-Hour Hotline: 0800-868-458
Email Address: drugsafety@taigenbiotech.com.tw
- Taiwan National Drug Adverse Reaction Center telephone: 02-23960100