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恩度 ENDOSTAR

Preparation guide for use with Recombinant Human Endostatin Injection

Read the entire contents prior to the preparation of Endostar and use under doctor's instruction

【Drug names】

Generic Name: Recombinant Human Endostatin Injection
Trade Name: ENDOSTAR
English Name: Recombinant Human Endostatin Injection
Chinese Name (Pinyin): Chongzu Ren Xueguanneipiyizhisu Zhusheye

【Composition】

Main Composition: Recombinant Human Endostatin
Source: Expressed by Escherichia coli
Excipients: Sodium acetate, Acetic acid, Mannitol

【Description】

Colorless transparent liquid. pH 5.5±0.5

【Indications】

ENDOSTAR + NP chemotherapy regimen is used to treat Stage III/IV NSCLC patients either untreated or pretreated. This indication is based on a completed multi-center Phase III clinical trial (see Clinical Studies).

【Strength】

15mg/3ml/vial (2.4×10^5 U/ vial)

【Dose and administration】

Add ENDOSTAR into 250~500ml NS just before the use, drip intravenously at uniform speed for 3~4h.

At combined administration with NP chemotherapy regimen, ENDOSTAR is administered continuously at 7.5mg/m^2 (1.2×10^5U/m^2) once a day during Day 1~14 of treatment cycle, and then continues the next treatment cycle only after the rest for 1 week (generally 2~4 treatment cycles). The physician is recommended to properly extend its administration time in clinical application within the tolerance of patients.

【Adverse Reactions】

During Phase I~III clinical trial, ENDOSTAR is administered in 470 advanced NSCLC patients. The frequent adverse reactions (1-10%) mainly occurred on heart, and rare adverse reactions (0.1-1%) mainly occurred in digestive system and skin/annexa allergy.

1. Heart: At the early stage of administration, few patients have mild fatigue, chest distress and palpitation. In most cases, these symptoms may improve enough so as not to influence the administration continuation after the symptomatic treatment. But they can persist to discontinue the administration in very few cases. A minority of cases had to stop the drug for the continuing above-mentioned symptoms. 30 patients (6.38%) have Degree I/II or mild/moderate cardiologic adverse reactions of mainly myocardial ischemia within Day 2~7 after the administration and posing no dangers to the patient's life. 6.4‰ of these cases have more evident but reversible symptoms, which does not influence the administration continuation but can alleviate without any symptomatic treatment. Only 2.1‰ of the cases stop the treatment due to adverse reactions. In the patients with previous coronary heart disease and hypertension, ENDOSTAR causes the following frequent cardiologic adverse reactions: sinus tachycardia, mild ST-T change, AV conduction blocking, atrial premature beat and rare ventricular premature beat. Thus, to guarantee patient safety, regular ECG examination is recommended for the patient with cardiologic adverse reactions during clinical application. The patient with previous serious heart diseases must use ENDOSTAR carefully under the guidance of physicians.

2. Digestive System: Rare diarrhea and liver dysfunction (mainly symptom-free transaminase elevation and jaundice). All these adverse reactions are mainly mild/moderate but rarely serious. Most are reversible and mild cases do not require symptomatic treatment; Moderate or serious cases may be alleviated through the slowing of dripping speed or through the proper symptomatic treatment after drug withdrawal; and only few cases require symptomatic treatment but generally have no influence on administration continuation.