

Summary of Investigation Results

Anamorelin Hydrochloride and Posaconazole

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	a. Anamorelin hydrochloride b. Posaconazole	a. Adlumiz Tablets 50 mg (Ono Pharmaceutical Co., Ltd.) b. Noxafil Tablets 100 mg, Noxafil for Intravenous Infusion 300 mg (MSD K. K.)
Japanese market launch	a. April 2021 b. Tablets 100 mg: April 2020 Intravenous Infusion 300 mg: July 2020	
Indications	a. • Cancer cachexia in the following malignancies: Non-small cell lung cancer, gastric cancer, pancreatic cancer, and colorectal cancer b. • Prophylaxis of deep mycosis in haematopoietic stem cell transplant patients or patients with haematological malignancy who are expected to have neutropenia. • Treatment of the following fungal infections: Invasive aspergillosis, fusarium infection, mucormycosis, coccidioidomycosis, chromoblastomycosis, mycetoma	
Summary of revisions	a. 1. “Patients receiving posaconazole” should be added to 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.). 2. “Posaconazole” should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS. b. 1. “Patients receiving anamorelin hydrochloride” should be added to 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.). 2. “Anamorelin hydrochloride” should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.	
Investigation	The pharmacokinetic effect of co-administration of anamorelin hydrochloride and	

results and background of the revision	posaconazole was evaluated. The strong inhibitory activity of posaconazole on CYP3A may increase the exposure to anamorelin hydrochloride, which is metabolized by CYP3A, thereby potentially exacerbating adverse reactions associated with anamorelin hydrochloride. The MHLW/PMDA concluded that revision of PRECAUTIONS was necessary. Of note, opinions regarding the impact of contraindicating co-administration of anamorelin hydrochloride and posaconazole in clinical settings were sought from relevant academic societies, confirming no specific major problems.
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