Pharmaceuticals and Medical Devices Safety Information

No. 417 February 2025

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This *Pharmaceuticals and Medical Devices Safety Information (PMDSI)* publication is issued reflective of safety information collected by the Ministry of Health, Labour and Welfare (MHLW). It is intended to facilitate safer use of pharmaceuticals and medical devices by healthcare providers. The PMDSI is available on the Pharmaceuticals and Medical Devices Agency (PMDA) web page (https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0002.html) and on the MHLW website (https://www.mhlw.go.jp/, only in Japanese).

Available information is listed here

Access to the latest safety information is available via the PMDA Medi-navi.

The PMDA Medi-navi is an e-mail mailing list service that serves to provide essential safety information released by the MHLW and PMDA. Subscribing to the Medi-navi will allow you to receive this information on the day of its release.
This service is available only in Japanese.

Register here

Published by
Ministry of Health, Labour and Welfare

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Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
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100-8916 Japan

Pharmaceuticals and Medical Devices Safety Information

No. 417 February 2025

Ministry of Health, Labour and Welfare
Pharmaceutical Safety Bureau, Japan

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E: Distribution of Dear Healthcare Professional Letters of Emergency Communications, *R:* Distribution of Dear Healthcare Professional Letters of Rapid Communications, *P*: Revision of PRECAUTIONS, *C*: Case Reports

Reporting of safety information such as adverse reactions to the Minister of Health, Labour and Welfare is a duty of healthcare professionals.

If healthcare professionals such as physicians, dentists, and pharmacists detect adverse reactions, infections, or malfunctions associated with drugs, medical devices, or regenerative medical products, please report them to the Minister of Health, Labour and Welfare directly or through the marketing authorization holder. As healthcare professionals, drugstore and pharmacy personnel are also required to report adverse reactions, etc.

Please utilize the Report Reception Site for reporting.
(This service is available only in Japanese.)

https://www.pmda.go.jp/safety/reports/hcp/0002.html

This English version of PMDSI is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Abbreviations

ADR	Adverse Drug Reaction
ALS	Amyotrophic Lateral Sclerosis
BT-PABA	N-Benzoyl-L-tyrosyl-p-aminobenzoic Acid
EPPV	Early Post-marketing Phase Vigilance
MAH	Marketing Authorization Holder
MHLW	Ministry of Health, Labour and Welfare
PFD	Pancreatic Function Diagnostant
PMDA	Pharmaceuticals and Medical Devices Agency
PSB	Pharmaceutical Safety Bureau
PSD	Pharmaceutical Safety Division

1

Revisions of PRECAUTIONS for pembrolizumab (genetical recombination) (pancreatic exocrine insufficiency)

1. Introduction

The MHLW issued a notification instructing the addition of “pancreatic exocrine insufficiency” to the 11.1 Clinically Significant Adverse Reactions section in the PRECAUTIONS of pembrolizumab (genetical recombination) (hereinafter referred to as “this drug”) on January 29, 2025.

“Pancreatic exocrine insufficiency” has not been included as an adverse reaction in the PRECAUTIONS for prescription drugs in Japan. Therefore, this article introduces the disease concept, etc. regarding pancreatic exocrine insufficiency.

2. Detail of the review

Precautions for “pancreatitis” have been included in the Clinically Significant Adverse Reactions section since this drug received marketing approval. As a result of evaluating overseas cases of pancreatic exocrine insufficiency, several cases for which a causal relationship between the drug and the event was reasonably possible were identified. Therefore, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Among the evaluated cases for which a causal relationship between the drug and pancreatic exocrine insufficiency was reasonably possible, some cases were confirmed where the existence of preceding pancreatitis is unclear.

3. Pancreatic exocrine insufficiency

(1) Disease concept

Pancreatic exocrine insufficiency is defined as follows in the Evidence-based Clinical Practice Guidelines for Chronic Pancreatitis:[1)]

Pancreatic exocrine insufficiency is a generic term for pathological conditions characterized by impaired digestion/absorption of the three major nutrients (carbohydrates, proteins, and fats) caused by a deficiency of pancreatic enzymes secreted from the pancreas to the duodenum due to an exocrine function disorder of the pancreas.

(2) Causes

The major diseases that cause the pancreatic exocrine insufficiency include chronic pancreatitis, post-pancreatectomy, post-acute necrotizing pancreatitis, autoimmune pancreatitis, and pancreatic tumour.[1)]

(3) Diagnosis and management

Pancreatic exocrine insufficiency indicates cases in which pancreatic exocrine function decreases to below 10 to 15% of that in healthy people. In Japan, it is defined as cases in which daily fat intake is 40 to 70 g/day and fecal fat excretion exceeds 5 g/day (fatty stool).[2)]

A diagnosis of pancreatic exocrine insufficiency is based on clinical signs, pancreatic enzyme levels, nutritional index markers, the BT-PABA test (PFD test), and diagnostic imaging. Pancreatic exocrine insufficiency causes various symptoms and signs including steatorrhoea, diarrhoea, abdominal distension, decreased weight, and deficiencies in vitamins (A, D, E, and K) due to impaired absorption of fat-soluble vitamins. Regarding blood biochemistry test values, a decrease

in nutritional index markers including blood protein, albumin, cholesterol, triglyceride, and hemoglobin, as well as a decrease in trace elements such as zinc and selenium, are characteristic findings.[1)]

Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures should be taken.

4. Closing remark

Healthcare professionals are requested to pay sufficient attention to the occurrence of pancreatic exocrine insufficiency associated with the use of this drug.

[Reference information]
Revisions of PRECAUTIONS (PSB/PSD Notification No.0129-1 dated January 29, 2025)
https://www.mhlw.go.jp/content/11125000/001387867.pdf (in Japanese)
English translation by the PMDA (January 29, 2025)
https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0012.html

[References]
1) Evidence-based Clinical Practice Guidelines for Chronic Pancreatitis 2021 (3rd Edition), compiled by the Japanese Society of Gastroenterology. Nankodo, 2021

2) Nakamura T, Takebe K, Kudoh K, et al. Steatorrhea in Japanese patients with chronic pancreatitis. J Gastroenterol 1995; 30: 79-83

2

Important Safety Information

Regarding the revision of the PRECAUTIONS of package inserts of drugs in accordance with the Notification dated January 29, 2025, this section will present the details of important revisions as well as the case summary serving as the basis for these revisions.

1 Injectable preparations containing arginine

Brand name (name of company)	[1] Plas-Amino Injection (200 mL bag, 500 mL bag) (Otsuka Pharmaceutical Factory, Inc.) [2] Twinpal Injection (500 mL, 1,000 mL) (AY Pharmaceuticals Co., Ltd.) [3] Bfluid Injection (500 mL bag, 1,000 mL bag) (Otsuka Pharmaceutical Factory, Inc.) [4] Argi-U Injection 20 g (AY Pharmaceuticals Co., Ltd.) [5] Arginine Injection “AY” 30 g (AY Pharmaceuticals Co., Ltd.)
Therapeutic category	Proteins, amino acid and preparations, agents affecting metabolism, n.e.c. (not elsewhere classified), reagents for various function test
Indications	[1] Amino acid supplementation under the following conditions: Hypoproteinaemia, undernutrition state, before/after surgery [2] Supplementation of amino acids, electrolytes, and water under the following conditions: •When the patient has poor oral intake with mild hypoproteinaemia or mild undernutrition •Before/after surgery [3] Supplementation of amino acid, electrolyte, vitamin B1, and water under the following conditions: ·When the patient has poor oral intake with mild hypoproteinaemia or mild undernutrition ·Before/after surgery [4] An emergent decrease in blood ammonia concentration in acute aggravation of hyperammonaemia under the following conditions, when it cannot be controlled by oral preparations: Congenital urea cycle disorder [Carbamoylphosphate synthetase deficiency, ornitine transcarbamylase deficiency, argininosuccinate synthetase deficiency (citrullinaemia), argininosuccinate lyase deficiency (argininosuccinic aciduria)] or lysinuric protein intolerance [5] This product is used for pituitary function tests. The normal response should be determined by individual institutions, but normally the peak is reached at 60 to 120 minutes after the start of injection in normal patients, with a blood growth hormone level of 10 ng/mL measured by radioimmunoassay. However, it is preferable to repeat the test to make a decision if the pre-dose blood growth hormone level is low and the highest level does not exceed 5 ng/mL.

PRECAUTIONS (Revised language is underlined.)

- •Plas-Amino Injection (200 mL bag, 500 mL bag)
- •Twinpal Injection (500 mL, 1,000 mL)
- •Argi-U Injection 20 g

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (newly added)	Patients with a history of hypersensitivity to any of the ingredients of this drug This drug should not be administered except in cases where such use is considered absolutely necessary for the treatment. Anaphylaxis may occur.
11. ADVERSE REACTIONS (newly added)	11.1 Clinically Significant Adverse Reactions Anaphylaxis

• Bfluid Injection (500 mL bag, 1,000 mL bag)

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (newly added)	Patients with a history of hypersensitivity to any of the ingredients of this drug (excluding those with a history of hypersensitivity to thiamine chloride hydrochloride) This drug should not be administered except in cases where such use is considered absolutely necessary for the treatment. Anaphylaxis may occur.
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions	Shock, anaphylaxis If decreased blood pressure, distressed feeling of chest, dyspnoea, etc. occur, administration should be discontinued immediately and appropriate measures should be taken.

• Arginine Injection “AY” 30 g

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (newly added)	Patients with a history of hypersensitivity to any of the ingredients of this drug This drug should not be administered except in cases where such use is considered absolutely necessary for the diagnosis. Anaphylaxis may occur.
11. ADVERSE REACTIONS (newly added)	11.1 Clinically Significant Adverse Reactions Anaphylaxis
Reference information	Number of cases (for which a causal relationship between the drug and event is reasonably possible) collected in the PMDA's database for adverse drug reactions, etc. reports [1] 0 [2] 1 (No patient mortalities) [3] 4 (No patient mortalities) [4] 1 (No patient mortalities) [5] 6 (No patient mortalities) Number of patients using the drug as estimated by the MAH during the previous 1-year period:

[1] Approximately 40,000
[2] Approximately 33,700
[3] Approximately 1,867,000
[4] Approximately 70
[5] Approximately 9,000

Japanese market launch:
[1] September 1982
[2] September 2004
[3] June 2006
[4] November 2000
[5] September 1981

Case summary

No.	Patient		Daily dose/ Administration duration	Adverse reaction	
	Sex/ age	Reason for use (complication)		Clinical course and treatment	
1	Female Under age of 10	A loading test of growth hormone/test for short stature	95 mL for 1 day	**Anaphylaxis**	
				Day of administration (day of completion of administration)	Arginine 95 ml was administered for arginine loading test.
				30 minutes after administration	Wheals and itching occurred on the patient's entire body. She complained of systemic urticaria and itching. Her blood pressure decreased to 86/36. Cyanosis developed. After administering 1 ampule of hydroxyzine hydrochloride, SpO_2 decreased to 80%. Oxygen 10L and normal saline were administered because she had a pale complexion and SpO_2 level was between 80% and 85%. Prednisolone 20 mg was intravenously injected, and oxygen 8L was additionally administered. Administration of normal saline and treatment by cooling the entire body were continued as her blood pressure recovered, and her condition was stabilized after 20 minutes. Although her condition initially stabilized, she had a pale complexion when she stood up to go to the bathroom. Her condition was resolving after bed rest. While wheals subsided, the itching persisted. She had no respiratory discomfort.
	Concomitant drugs: None				

Case summary

<table>
<tr><th rowspan="2">No.</th><th colspan="2">Patient</th><th rowspan="2">Daily dose/
Administration duration</th><th colspan="2">Adverse reaction</th></tr>
<tr><th>Sex/
age</th><th>Reason for use
(complication)</th><th colspan="2">Clinical course and treatment</th></tr>
<tr><td rowspan="4">1</td><td rowspan="4">Male
Under age of 10</td><td rowspan="4">Loading test for short stature</td><td rowspan="4">13 g
Once</td><td colspan="2">Anaphylaxis (dyspnoea, vomiting, abdominal pain)</td></tr>
<tr><td>Day 1 of administration (day of completion of administration)</td><td>L-Arginine hydrochloride (Arginine Injection “AY” 30 g) was administered by intravenous infusion.</td></tr>
<tr><td>Within 30 minutes after start of administration</td><td>A cough developed. Thereafter, erythema (urticaria) over the entire body, dyspnoea, and abdominal pain occurred.
Administration of adrenaline (intravenous infusion, inhalation), hydroxyzine (drip infusion), and prednisolone sodium succinate (intravenous infusion) was initiated.
A decrease in blood pressure was not observed.
Symptoms improved after the drugs described above were administered.
Discharge from the hospital was postponed for monitoring.</td></tr>
<tr><td>1 day after administration</td><td>No biphasic reaction was observed.
Therefore, the patient was discharged.</td></tr>
<tr><td colspan="6">Laboratory test value
<table>
<tr><th>Test item (unit)</th><th>Day of administration (Before start of administration)</th><th>Day of administration (15 minutes after administration)</th><th>Day of administration (21 minutes after administration)</th></tr>
<tr><td>Systolic blood pressure (mmHg)</td><td>117</td><td>94</td><td>126</td></tr>
<tr><td>Diastolic blood pressure (mmHg)</td><td>77</td><td>78</td><td>66</td></tr>
</table></td></tr>
<tr><td colspan="6">Suspected concomitant drugs: None
Concomitant drugs: None</td></tr>
</table>

3

Revisions of PRECAUTIONS (No. 357)

This section presents details of revisions to the PRECAUTIONS and brand names of drugs that have been revised in accordance with the Notifications dated January 29, 2025.

1 Proteins, amino acid and preparations, agents affecting metabolism, n.e.c. (not elsewhere classified)

[1] Twinpal Injection
[2] Plas-Amino Injection
[3] Argi-U Injection 20 g

Brand name	[1] Twinpal Injection (500 mL, 1,000 mL) (AY Pharmaceuticals Co. ,Ltd.) [2] Plas-Amino Injection (200 mL bag, 500 mL bag) (Otsuka Pharmaceutical Factory, Inc.) [3] Argi-U Injection 20 g (AY Pharmaceuticals Co., Ltd.)
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS	Patients with a history of hypersensitivity to any of the ingredients of this drug This drug should not be administered except in cases where such use is considered absolutely necessary for the treatment. Anaphylaxis may occur.
9.1 Patients with Complication or History of Diseases, etc. (newly added)	
11. ADVERSE REACTIONS (newly added)	11.1 Clinically Significant Adverse Reactions Anaphylaxis

2 Proteins, amino acid and preparations

Bfluid Injection

Brand name	Bfluid Injection (500 mL bag, 1,000 mL bag) (Otsuka Pharmaceutical Factory, Inc.)
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS	Patients with a history of hypersensitivity to any of the ingredients of this drug (excluding those with a history of hypersensitivity to thiamine chloride hydrochloride) This drug should not be administered except in cases where such use is considered absolutely necessary for the treatment.
9.1 Patients with Complication or History of Diseases, etc. (newly added)	Anaphylaxis may occur.
11. ADVERSE REACTIONS	Shock, anaphylaxis
11.1 Clinically Significant Adverse Reactions	If decreased blood pressure, distressed feeling of chest, dyspnoea, etc. occur, administration should be discontinued immediately and appropriate measures should be taken.

3 Anticoagulants

Edoxaban tosilate hydrate

Brand name	Lixiana Tablets 15 mg, 30 mg, 60 mg, Lixiana OD Tablets 15 mg, 30 mg, 60 mg (Daiichi Sankyo Co., Ltd.)
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (newly added)	Thrombocytopenia

4 Other antitumor agents

Pembrolizumab (genetical recombination)

Brand name	Keytruda Injection 100 mg (MSD K.K.)
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions	Pancreatitis, pancreatic exocrine insufficiency

5 Reagents for various function tests

Arginine Injection “AY” 30 g

Brand name	Arginine Injection “AY” 30 g (AY Pharmaceuticals Co., Ltd.)
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (newly added)	Patients with a history of hypersensitivity to any of the ingredients of this drug This drug should not be administered except in cases where such use is considered absolutely necessary for the diagnosis. Anaphylaxis may occur.
11. ADVERSE REACTIONS (newly added)	11.1 Clinically Significant Adverse Reactions Anaphylaxis

4

List of Products Subject to Early Post-marketing Phase Vigilance

Early Post-marketing Phase Vigilance (EPPV) was established in 2001. This unique system for newly-approved drug products refers to any safety assurance activities that are conducted within a period of 6 months just after marketing of a new drug. The MAH responsible for a new drug in the EPPV period is required to collect adverse drug reactions (ADRs) data from all medical institutions where the drug is used and to take safety measures as appropriate. The aim of EPPV is to promote the rational and appropriate use of drugs in medical treatments and to facilitate prompt action for the prevention of serious ADRs. EPPV is specified as a condition of product approval.

(As of January 31, 2025)
◎: Products for which EPPV was initiated after December 1, 2024

	Nonproprietary name / Brand name	Name of the MAH	Date of EPPV initiatation
◎	Insulin Icodec (genetical recombination) Awiqli injection FlexTouch 300 units, 700 units	Novo Nordisk Pharma Ltd.	January 30, 2025
◎	Articaine hydrochloride/adrenaline bitartrate Septocaine Combination Injection Cartridge	GC SHOWAYAKUHIN CORPORATION	January 21, 2025
◎	Amifampridine phosphate Firdapse Tablets 10 mg	DyDo Pharma, Inc.	January 15, 2025
◎	Benralizumab (genetical recombination)[*1] Fasenra Subcutaneous Injection 30 mg Syringe	AstraZeneca K.K.	December 27, 2024
◎	Efgartigimod alfa (genetical recombination)/vorhyaluronidase alfa (genetical recombination)[*2] Vyvdura Combination Subcutaneous Injection	argenx Japan K.K.	December 27, 2024
◎	Daridorexant hydrochloride Quviviq Tablets 25 mg, 50 mg	Nxera Pharma Japan Co., Ltd.	December 19, 2024
◎	Aceneuramic acid Acenobel Extended Release Tablets 500 mg	Nobelpharma Co., Ltd.	December 19, 2024
◎	Estetrol hydrate/drospirenone alyssa combination tablets	Fuji Pharma Co., Ltd.	December 3, 2024
	Donanemab (genetical recombination) kisunla Intravenous Infusion 350 mg	Eli Lilly Japan K.K.	November 26, 2024
	Fruquintinib	Takeda Pharmaceutical	November 22,

Nonproprietary name Brand name		Name of the MAH	Date of EPPV initiatation
	Fruzaqla capsules 1 mg, 5 mg	Company Limited	2024
	Sacituzumab govitecan (genetical recombination)	Gilead Sciences K.K.	November 20, 2024
	Trodelvy for Injection 200 mg		
	Amivantamab (genetical recombination)	Janssen Pharmaceutical K.K.	November 20, 2024
	Rybrevant Intravenous Infusion 350 mg		
	Repotrectinib	Bristol-Myers Squibb K.K.	November 20, 2024
	Augtyro capsules 40 mg		
	Mecobalamin[*3]	Eisai Co., Ltd.	November 20, 2024
	Rozebalamin for Injection 25 mg		
	Teprotumumab (genetical recombination)	Amgen K.K.	November 20, 2024
	Tepezza for Intravenous Infusion 500 mg		
	Voclosporin	Otsuka Pharmaceutical Co., Ltd.	November 20, 2024
	Lupkynis Capsules 7.9 mg		
	Tasurgratinib succinate	Eisai Co., Ltd.	November 20, 2024
	Tasfygo Tablets 35 mg		
	Avibactam sodium/ceftazidime hydrate	Pfizer Japan Inc.	November 12, 2024
	Zavicefta Combination for Intravenous Infusion		
	Tapinarof	Japan Tobacco Inc.	October 29, 2024
	Vtama cream 1%		
	Gumarontinib hydrate	Haihe Biopharma K.K.	October 11, 2024
	Haiyitan tablets 50 mg		
	Live attenuated influenza vaccine	Daiichi Sankyo Co., Ltd.	October 3, 2024
	Flumist Intranasal Spray		
	Coronavirus (SARS-CoV-2) RNA vaccine[*4]	Meiji Seika Pharma Co., Ltd.	September 30, 2024
	Kostaive intramuscular injection		
	Brexpiprazole[*5]	Otsuka Pharmaceutical Co., Ltd.	September 24, 2024
	Rexulti tablets 1 mg, 2 mg, Rexulti OD tablets 0.5 mg, 1 mg, 2 mg		
	Treprostinil[*6]	Mochida Pharmaceutical Co., Ltd.	September 24, 2024
	Treprost Inhalation Solution 1.74 mg		
	Inactivated tissue culture tick-borne encephalitis vaccine	Pfizer Japan Inc.	September 13, 2024
	Ticovac suspension liquid for intramuscular injection 0.5 mL, Ticovac Junior suspension liquid for intramuscular injection 0.25 mL		
	Freeze-dried human protein C concentrate	Takeda Pharmaceutical Company Limited	September 6, 2024

Nonproprietary name Brand name		Name of the MAH	Date of EPPV initiatation
	Ceprotin for Intravenous Injection 1000 IU		
	Pneumococcal 20-valent conjugate vaccine adsorbed (mutated diphtheria CRM_{197} conjugate)[*7] Prevenar 20 Suspension Liquid for Injection	Pfizer Japan Inc.	August 30, 2024
	Brivaracetam Briviact Tablets 25 mg, 50 mg	UCB Japan Co. Ltd.	August 30, 2024
	Mepolizumab (genetical recombination)[*8] Nucala solution for s.c. injection 100 mg	GlaxoSmithKline K.K.	August 28, 2024
	Maribavir Livtencity tablets 200 mg	Takeda Pharmaceutical Company Limited	August 28, 2024
	Pirtobrutinib Jaypirca Tablets 50 mg, 100 mg	Eli Lilly Japan K.K.	August 21, 2024
	Zinc histidine hydrate Zintus Tablets 50 mg	Nobelpharma Co., Ltd.	August 20, 2024
	Momelotinib hydrochloride hydrate Omjjara Tablets 100 mg, 150 mg, 200 mg	GlaxoSmithKline K.K.	August 15, 2024
	Iptacopan hydrochloride hydrate Fabhalta capsules 200 mg	Novartis Pharma K.K.	August 15, 2024
	Favipiravir[*9] Avigan Tablets 200 mg	FUJIFILM Toyama Chemical Co., Ltd.	August 15, 2024

*1 Eosinophilic granulomatosis with polyangiitis in patients who have not sufficiently responded to conventional treatments

*2 Chronic inflammatory demyelinating polyradiculoneuritis

*3 Slowing the progression of functional impairment in amyotrophic lateral sclerosis (ALS)

*4 Prevention of disease caused by SARS-CoV-2 infection (COVID-19)

*5 Excessive motor activity or physically/verbally aggressive behavior due to rapid changes in mood, irritability, and/or outbursts associated with dementia due to Alzheimer's disease

*6 Pulmonary hypertension associated with interstitial lung disease

*7 Prophylaxis of pneumococcal disease (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V,10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F) in the elderly and individuals who are considered to be at high risk of pneumococcal disease

*8 Chronic sinusitis with nasal polyps (for use only in patients who have not sufficiently responded to conventional treatments)

*9 Severe fever with thrombocytopenia syndrome virus infection