藥品異動通知 107.02.01

藥品新增

<20P069> Pomalidomide(4mg)(Pomalyst®)膠囊.注意劑量

新藥介紹

<20P069> Pomalidomide(4mg)(Pomalyst®)膠囊.注意劑量

藥理作用/作用機轉	Pomalidomide induces cell cycle arrest and apoptosis directly in multiple myeloma cells. It enhances T cell- and natural killer (NK) cell-mediated cytotoxicity, inhibits production of proinflammatory cytokines tumor necrosis factor-α (TNF-α), IL-1, IL-6, and IL-12, and inhibits angiogenesis.
適應症/劑量	**PO** **Adult:** Note: ANC should be ≧500 cells/mm^3 and platelets ≧50,000 cells/mm^3 prior to initiating new cycles of therapy. **Multiple myeloma, relapsed/refractory:** 4 mg QD on days 1 to 21 of 28-day cycles (in combination with dexamethasone); continue until disease progression or unacceptable toxicity. Dosage adjustment for therapy with strong CYP1A2 inhibitors (ex.Ciproxin): Avoid concomitant use of strong CYP1A2 inhibitors. If concomitant use of strong CYP1A2 inhibitors cannot be avoided, reduce the pomalidomide dose by 50%. Dexamethasone 的建議劑量為，在每個 28 天療程的第 1 天、第 8 天、第 15 天和第 22 天，每日一次口服 40mg。
使用禁忌	Pregnancy. Hypersensitivity to pomalidomide, thalidomide, lenalidomide, or any component of the formulation; breast-feeding; women of childbearing potential not using 2 effective means of contraception; male patients unable to comply with required contraceptive measures.
不良反應	Fever, peripheral edema, fatigue, dizziness, headache, Skin rash, pruritus, hypercalcemia, hypokalemia, hyperglycemia, hyponatremia, dehydration, constipation, nausea, diarrhea, decreased appetite, weight loss, vomiting, neutropenia, anemia, thrombocytopenia, leukopenia,weakness, back pain, musculoskeletal chest pain, arthralgia, musculoskeletal pain, increased serum creatinine, renal failure, upper respiratory tract infection, pneumonia, cough, epistaxis, pneumonia, acute cytolytic hepatitis, acute hepatoxicity, acute myelocytic, leukemia increased liver enzymes, pulmonary fibrosis.
懷孕用藥分級(FDA)	NA
健保規範	01)與 dexamethasone 合併使用且先前接受過含 lenalidomide 和 bortezomib 至少兩種治療失敗之多發性骨髓瘤。
其他	1. 不得壓碎、咀嚼或打開膠囊。 2. 可空腹或與食物併服。 3. 治療期間，及停藥後1個月內不得捐血，以免懷孕女性接受該血液後損及

	胎兒。
藥品圖檔	 Pomalyst® 4 mg hard capsules, pomalidomide 2 1 0 cm 更新日期:2018.01.30

藥品異動通知 107.02.01

藥品新增

<14P072> Alirocumab (75mg/ml) (Praluent®)針.自費

新藥介紹

<14P072> Alirocumab (75mg/ml) (Praluent®)針.自費

藥理作用/作用機轉	Alirocumab is a human monoclonal antibody (IgG1 isotype) that binds to proprotein convertase subtilisin kexin type 9 (PCSK9). **PCSK9** binds to the low-density lipoprotein receptors (LDL-R) on hepatocyte surfaces to promote LDL-R degradation within the liver. LDL-R is the primary receptor that clears circulating LDL; therefore, the decrease in LDL-R levels by PCSK9 results in higher blood levels of LDL-C. By inhibiting the binding of PCSK9 to LDL-R, alirocumab increases the number of LDL-Rs available to clear LDL, thereby lowering LDL-C levels.
適應症/劑量	SC, **Adult:** **Hyperlipidemia, primary:** 75 mg every 2 weeks or 300 mg every 4 weeks. If an adequate LDL-C response is not achieved, may increase or modify dosing regimen to a maximum of 150 mg every 2 weeks. *Missed dose:* If a dose is missed ≤7 days from the usual day, the dose as soon as possible and then resume the original schedule; if missed > 7 days, skip the missed dose and resume the normal dosing schedule, or if dosage is monthly, start a new schedule based on this date.
使用禁忌	Serious hypersensitivity to alirocumab or any component of the formulation.
不良反應	【L】Diarrhea, liver enzyme disorder, influenza, injection site reaction, myalgia, cough. 【R】Hypersensitivity angiitis, pruritus, skin rash, urticarial, memory impairment.
懷孕用藥分級(FDA)	NA
健保規範	NA/自費
其他	1. 從冰箱拿出後置放於 25˚C 以下的時間最多不得超過 24 小時。 2. 若漏打一次劑量，病患應儘快於漏打後七天內補打該次藥物，並依原注射時程繼續治療。若未能於漏打後七天內補打該次注射藥物，則不須補打，依原注射時程繼續治療。若療程是一個月一次則當下重新開始。
品圖檔	

藥品異動通知 107.02.01

藥品新增

<10H006> AdaliMumab(40mg)(Humira®)針.syringe

新藥介紹

<10H006> AdaliMumab(40mg)(Humira®)針.syringe

藥理作用/作用機轉	Adalimumab is a recombinant monoclonal antibody that binds to human tumor necrosis factor alpha (TNF-α), thereby interfering with binding to TNFα receptor sites and subsequent cytokine-driven inflammatory processes. Elevated TNF levels in the synovial fluid are involved in the pathologic pain and joint destruction in immune-mediated arthritis. Adalimumab decreases signs and symptoms of psoriatic arthritis, rheumatoid arthritis, and ankylosing spondylitis. It inhibits progression of structural damage of rheumatoid and psoriatic arthritis. Reduces signs and symptoms and maintains clinical remission in Crohn disease and ulcerative colitis; reduces epidermal thickness and inflammatory cell infiltration in plaque psoriasis.
適應症/劑量	**SC** **Adult:** ●**Ankylosing spondylitis、Psoriatic arthritis:** 40 mg Q2W (may continue MTX, DMARDs, corticosteroids, NSAIDs ,analgesics). ●**Rheumatoid arthritis:** 40 mg Q2W (may continue MTX, DMARDs, corticosteroids, NSAIDs ,analgesics); patients not taking concomitant MTX may increase dose to 40 mg QW. ●**Crohn's disease、Ulcerative colitis:** (may continue aminosalicylates and/or corticosteroids; if necessary, azathioprine, mercaptopurine, or methotrexate may also be continued): *Initial: 160 mg (160mg a day **or** 80mg on consecutive 2 days), then 80 mg 2 weeks later (day 15). *Maintenance: 40 mg Q2W beginning day 29. ◯**Note:** Some patients may require 40 mg QW as maintenance therapy. (**Crohn's disease**) ◯**Note:** Only continue maintenance dose in patients demonstrating clinical remission by 8 weeks (day 57) of therapy. **(Ulcerative colitis)** ●**Plaque psoriasis、Uveitis:** *Initial: 80 mg as a single dose *Maintenance: 40 mg Q2W beginning 1 week after initial dose. ●**Hidradenitis suppurativa:** *Initial: 160 mg (160mg a day **or** 80mg on consecutive 2 days), then 80 mg 2 weeks later (day 15). *Maintenance: 40 mg QW beginning day 29. **Pediatric:** ●**Crohn disease**: Children≧6 years and Adolescents: 17 kg to <40 kg:

	* Initial: 80 mg (given on day 1), then 40 mg 2 weeks later (day 15). * Maintenance: 20 mg Q2W beginning week 4 (day 29). ≧40 kg: * Initial: 160 mg (160mg a day **or** 80mg on consecutive 2 days), then 80 mg 2 weeks later (day 15; given as two 40 mg on the same day). * Maintenance: 40 mg Q2W beginning week 4 (day 29). ●**Juvenile idiopathic arthritis (JIA)**: Children≧2 years and Adolescents: May continue MTX, corticosteroids, NSAIDs, analgesics. *10 to <15 kg: 10 mg Q2W. *15 to <30 kg: 20 mg Q2W. *≧30 kg: 40 mg Q2W. ●**Uveitis:** Children≧4 years and Adolescents: BSA-directed dosing: * 24 or 40 mg/m^2 Q2W; Max. 40 mg/dose. Weight-directed dosing: * <30 kg: 20 mg Q2W * >30 kg: 40 mg Q2W
使用禁忌	Known hypersensitivity to adalimumab or any component of the formulation; severe infection (eg, sepsis, tuberculosis, opportunistic infection); moderate-to-severe heart failure.
不良反應	【M】 Injection site pain, injection site reaction, headache, upper respiratory infection, rash, sinusitis. 【L】Hypersensitivity reaction, infectious disease. 【R】Demyelinating disease of central nervous system, peripheral demyelinating neuropathy.
懷孕用藥分級(FDA)	NA
健保規範	01)2 歲至 17 歲的兒童具有活動性多關節幼年型慢性關節炎 02)成人類風濕關節炎 03)僵直性脊椎炎 04)乾癬性周邊關節炎 05)乾癬性脊椎病變 06)乾癬 07)成人克隆氏症 08)兒童克隆氏症 09)潰瘍性結腸炎
其他	1.可儲存在不高於25度之室溫中單次儲存達14 天，且須避光儲存，若於室溫儲存14天內未使用即應丟棄。
藥品圖檔