24 July 2019

To whom it concerns,

**RE: Labelling exemption to allow release of Australian registered stock of SYNACTHEN Solution for Injection 0.25 mg/1mL to New Zealand.**

Juno Pharmaceuticals NZ Ltd is the sponsor for Synacthen solution for injection 0.25 mg/1 mL in New Zealand and Australia. This product is distributed by Link Healthcare in both markets.

At the request of Link Healthcare and PHARMAC, Juno submitted a labelling exemption to Medsafe to allow for the release of Australian registered stock to New Zealand to mitigate a medicine shortage of New Zealand registered stock.

The labelling exemption was granted on 11 July 2019 and is valid until 10 July 2021. The labelling exemption is also valid for batch C19011of Synacthen only.

With respect to differences between the product registered in Australia and New Zealand, the products are identical with respect to manufacturing and testing. With respect to packaging, labelling and product ordering description, the following differences are apparent:

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|  | **New Zealand product** | **Australian product** |
| **Product Ordering Descriptions** | **Unavailable** | LHC Code 102060 AU Synacthen 0.25mg/1mL (Tetracosactrin) amp x 1**Available** |
| **Label** |  |  |
| Route of administration | States I.M. and I.V. only | States I.M. only |
| **Carton** |  |  |
| Route of administration | States I.M. and I.V. only | States I.M. only |
| Market | Multi country | Australia only |
| Language | English, Italian, French | English only |
| **Leaflet** |  |  |
| Indication | For the investigation of adrenocortical insufficiencyAs an alternative to Synacthen Depot in the following indications where I.V. injection or infusion of tetracosactide is preferable to I.M. injectionNeurological diseases:acute exacerbations in patients suffering from multiple sclerosisWest syndrome (infantile muoclonic encephalopathy with hypsarrhythmia)Rheumatic diseases:short-term therapy in conditions for which glucocorticoids are normally indicated; in patients showing poor gastrointestinal tolerance of oral glucocorticoids; whereglucocorticoids in normal doses have not elicited an adequate response.Skin diseases:Long-term treatment of skin disorders responsive to glucocorticoids - e.g. pemphigus,severe chronic eczema, erythrodermal or pustular forms of psoriasis.Diseases of the gastrointestinal tract:Ulcerative colitis; regional enteritis.Oncology:As adjuvant therapy to improve the tolerability of chemotherapy. | As a diagnostic aid in the assessment of suspected adrenocortical hypofunction. |
| Dosage and Administration | 30-minute Synacthen test:Plasma cortisol is measured immediately before and exactly 30 minutes after an injection of 250 micrograms Synacthen I.M. or I.V. If plasma cortisol increases by >200 nmol/L (70 micrograms/L), i.e. if the value 30 minutes after injection is >500 nmol/L (180 micrograms/L), adrenocortical function is regarded as normal. All the plasma samples should be stored in a refrigerator kept until plasma cortisol level estimation.Special populations:Renal impairment:No studies have been performed in patients with renal impairment.Hepatic impairment:No studies have been performed in patients with hepatic impairment.Elderly patients: There is no such information available which would necessitate dosage modification in elderly (65 years of age and above).If the 30-minute test gives inconclusive results, or if the aim is to determine the functional reserve of the adrenal cortex, the 5-hour test may be performed using Synacthen Depot (see Synacthen Depot Data Sheet).Therapeutic useFor therapeutic indications, Synacthen can be administered as an I.V. injection or as an infusion in glucose solution (5% or 12.5%) or NaCl (0.9%) (see also Pharmaceutical information) | Synacthen 30 Minute Test This test is based on the increase in plasma cortisol recorded 30 minutes after an intramuscular injection of Synacthen 250 micrograms. Two blood specimens should be taken, the first immediately before and the second exactly 30 minutes after the injection of Synacthen. If the plasma cortisol rises to at least 200 nanomoles/L (70 micrograms/L) above the initial level, or if the plasma cortisol level attained 30 minutes after injection exceeds 500 nanomoles/L (180 micrograms/L), irrespective of the basal level, then adrenocortical function can be regarded as normal. |
| Contraindications | Known hypersensitivity to tetracosactide and/or ACTH or to any of the excipients listed in section 6.1 List of excipients. Synacthen must not be used to treat asthma or other allergic conditions due to the increased risk of anaphylactic reactions (also see section 4.4 Special Warnings and precautions). Acute psychosis Infectious diseases. Peptic ulcer. Refractory heart failure. Cushing's syndrome. Treatment of primary adrenocortical insufficiency. Adrenogenital syndrome | If the patient's case history discloses any record of hypersensitivity reactions to ACTH treatment, tetracosactrin must not be used. Hypersensitivity to tetracosactrin and / or ACTH of animal origin or to any component of the formulation. Synacthen must not be used to treat asthma or other allergic conditions due to the increased risk of anaphylactic reactions (also see PRECAUTIONS). Viral diseases or recent vaccination with live virus. Acute psychoses. Infections (unless antibiotics are being administered at the same time). Peptic ulcer. Cushing's syndrome. Heart failure (refractory). |

I trust the information provided is satisfactory. However, should you wish to discuss this application, please do not hesitate to contact the undersigned.

Yours sincerely,

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