Notification of disposition of request for variances

Certificate #: 34554-36337-1 -C 4

The minor variation committee, of the Public Health Policy and Liciensing Sector of the Ministry of Health & Prevention has approved the requested changes , shown below.

Registartion No.	**34554-36337-1**
Product Name	Tremfya® 100 mg/mL Pre-Filled Syringe
Pack Strength	100 mg/ml
Pack Size(s)	1 ml Pre-Filled Syringe x1
Marketing Authorozation Holder	Janssen Cilag International N.V. ,Beerse,BELGIUM
Manufacturer	CILAG AG,Schaffhausen,Switzerland
Authorized Agent	CITY MEDICAL STORE
Pharmaceutical Form	Solution for - Injection

MINOR CHANGE DETAILS:

Issued on: 24/01/2021
Pass Code: 157637

هذه الشهادة صادرة من وزارة الصحة ووقاية المجتمع وتعتبر من الوثائق الحكومية الرسمية ولا تحتاج إلى توقيع، ويحظر قطعيا تقليدها أو إدخال أي تعديلات عليها سواءً بالإضافة أو الحذف أو التغيير في بياناتها أو غير ذلك من أنواع التعديل، وتعد الشهادة لاغية إذا شابهها شيء من ذلك. للتأكد من صلاحية الشهادة يرجى المسح الضوئي للرمز ثنائي الأبعاد.

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Updated Data Pack Details	Old Value	New Value
Indication	Tremfya is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Tremfya is used to treat adults with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin and nails. Tremfya can improve the condition of the skin and appearance of nails and reduce symptoms, such as scaling, shedding, flaking, itching, pain and burning.	Tremfya contains the active substance guselkumab which is a type of protein called a monoclonal antibody. This medicine works by blocking the activity of a protein called IL-23, which is present at increased levels in people with psoriasis and psoriatic arthritis. Plaque psoriasis Tremfya is used to treat adults with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin and nails. Tremfya can improve the condition of the skin and appearance of nails and reduce symptoms, such as scaling, shedding, flaking, itching, pain and burning. Psoriatic arthritis Tremfya is used to treat a condition called “psoriatic arthritis”, an inflammatory disease of the joints, often accompanied by psoriasis. If you have psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Tremfya to reduce the signs and symptoms of the disease. Tremfya can be used alone or with another medicine named methotrexate. Using Tremfya in psoriatic arthritis will benefit you by reducing the signs and symptoms of the disease, slowing down the damage to the cartilage and bone of the joints and improving your ability to do normal daily activities.

DATE OF IMPLEMENTATION IS SIX MONTHS FROM THE DATE OF THE CERTIFICATE

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