Thornton & Ross
STADA GROUP

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Date: 25 November 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Movymia 20 micrograms/80 microliters solution for injection▼ (teriparatide): Interim Supply of French Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: STADA Arzneimittel AG is currently experiencing supply disruption with Movymia 20 micrograms / 80 microliters solution for injection▼ (teriparatide) in the UK (Great Britain and Northern Ireland).

To ensure continuity in supply, STADA Arzneimittel AG has obtained approval from the MHRA to supply French product (batch number E35006AA; 3000 units) which are expected to be on the UK (Great Britain) market from November 2024 to December 2024.

Please note the following:

- This product is considered licensed in the UK.
- The product from France has the same formulation as the UK product
- The product from France is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are differences between the French and UK product information. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- A copy of the UK patient information leaflet is provided and should be provided to the patient.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/10780/ or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012 and Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Movymia 20 micrograms / 80 microliters solution for injection and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Please see the below table, images of the French packs to be provided.

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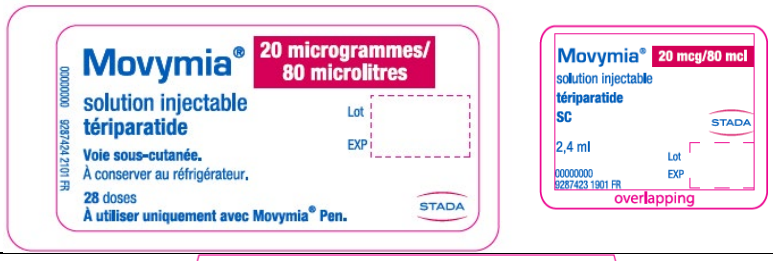
Inner labelling	
Outer carton	

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website

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- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

- Movymia 20 micrograms/80 microliters solution for injection ▼ is subject to additional monitoring. This will allow quick identification of new safety information
- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle ▼ to the MHRA through the Yellow Card Scheme.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point
If you have any questions about this letter or require more information about Movymia 20 micrograms/80 microliters solution for injection ▼, please contact Thornton & Ross Ltd. Medical Information at telephone +44(0)1484 848164 or e-mail thorntonross@medinformation.co.uk.

Yours faithfully,

Mr James Boss
Regulatory Affairs Officer
Thornton & Ross Ltd. (on behalf of the licence holder, STADA Arzneimittel AG)