Abbreviated Prescribing Information

Movymia® Teriparatide

▼ Movymia 20 micrograms/80 microlitres solution for injection Prescribing Information.

Please refer to the Summary of Product Characteristics before prescribing Movymia.

Presentation: Each cartridge of 2.4 mL of solution contains 600 µg of teriparatide (corresponding to 250 µg per mL).

Indication: In adults for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures, but not hip fractures has been demonstrated. Treatment of osteoporosis associated with sustained glucocorticoid therapy at increased risk of fracture.

Dosage and administration: Administered once daily by subcutaneous injection in the thigh or abdomen using the Movymia Pen. Adults – Recommended dose is 20 µg administered once daily. Patients should receive supplemental calcium/vitamin D supplements if dietary intake is inadequate. Maximum duration of use is 24 months and this course of treatment should not be repeated over a patient's lifetime. Renal impairment – Not to be used in patients with severe renal impairment; caution is advised for patients with moderate renal impairment. Hepatic impairment – Caution is advised. Paediatric population and young adults with open epiphyses – Should not be used.

Contraindications: Hypersensitivity to the active or any of the excipients. Pregnancy and breast-feeding. Pre-existing hypercalcaemia. Severe renal impairment. Metabolic bone diseases (inc. hyperparathyroidism and Paget's disease) other than primary osteoporosis/glucocorticoid-induced osteoporosis. Unexplained elevation of alkaline phosphatase. Prior external beam or implant radiation therapy to the skeleton. Patients with skeletal malignancies or bone metastases.

Warnings and Precautions: *Serum and urine calcium* – In normocalcaemic patients, slight and transient elevations of serum calcium concentrations have been observed; any blood samples for serum calcium measurements should be taken at least 16 hours after the most recent injection. Routine calcium monitoring during therapy is not required. Teriparatide may cause small increases in urinary calcium excretion. *Urolithiasis* – Caution is advised in patients with active or recent urolithiasis due to the potential exacerbation of this condition. *Orthostatic hypotension* – Isolated episodes of transient orthostatic hypotension have been observed, typically within 4 hours of treatment, and had been resolved within a few minutes/hours by placing the patient in a reclining position. This did not preclude continued treatment. *Renal impairment* – Caution is advised in patients with moderate renal impairment. *Younger adult population* – Experience in younger adults (inc. pre-menopausal women) is limited and treatment should only be initiated where the benefit clearly outweighs the risk.

Fertility, pregnancy and lactation: Women of child-bearing potential should use effective methods of contraception and if pregnancy occurs, treatment should be discontinued. This product is contraindicated in pregnancy and breast-feeding, effect on fertility is unknown.

Undesirable effects: *Serious common side effects:* Syncope, hiatus hernia; *Other serious side effects:* Tachycardia, nephrolithiasis, anaphylaxis, renal failure; *Other very common side effects:* Pain in the limb; *Other common side effects:* Anaemia, hypercholesterolaemia, depression, dizziness, headache, sciatica, vertigo, palpitations, hypotension, dyspnoea, nausea, vomiting, gastro-oesophageal reflux disease, sweating increased, muscle cramps, fatigue, chest pain, asthenia, mild and transient injection site events, including pain, swelling, erythema, localised bruising, pruritus, minor bleeding at injection site. For full list of side effects, consult SmPC.

Special precautions for storage: Once in use, the pen should be stored in the refrigerator between doses and a new sterile pen needle must be used for each injection. Do not freeze. Protect from light. Do not store with the needle attached.

Legal Category: POM.

Pack size and price: 1 carton of Movymia 2.4 mL cartridge and 1 pen pack (£235) and 1 carton of Movymia 2.4 mL cartridge (£235).

MA Number: PLGB 11204/0337

MA Holder: STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany.

UK Distributor: Thornton & Ross Ltd, Linthwaite, Huddersfield, West Yorkshire, HD7 5QH. *Full SmPC available from the UK Distributor.*

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Medical Information on 01484 848164.