Prescribing Information Terrosa® ▼(teriparatide)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: Terrosa 20 micrograms/80 microliters solution for injection. One cartridge of 2.4mL of solution contains 600 micrograms of teriparatide (corresponding to 250 micrograms per mL).

Indications: Adults. 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 systemic glucocorticoid therapy in women and men at increased risk for fracture.

Dosage and administration: The recommended dose is 20 micrograms administered once daily. Patients should receive supplemental calcium and vitamin D supplements if dietary intake is inadequate. The maximum total duration of treatment with teriparatide should be 24 months. The 24-month course of teriparatide should not be repeated over a patient's lifetime. Following cessation of teriparatide therapy, patients may be continued on other osteoporosis therapies. Severe renal impairment: contraindicated. Moderate renal impairment: use with caution. Mild renal impairment: no special caution. Hepatic impairment: no data are available, use with caution. Children: Teriparatide should not be used in paediatric patients (less than 18 years), or young adults with open epiphyses. Elderly: no dose adjustment required.

Method of administration: Terrosa should be administered once daily by subcutaneous injection in the thigh or abdomen. It should be administered exclusively with the Terrosa Pen reusable, multidose medicine delivery system and the injection needles which are listed as compatible in the instructions which are provided with the pen. The pen and injection needles are not included with Terrosa. Terrosa must not be used with any other pen. Patients must be trained to use the proper injection techniques. An instruction for use which is included in the carton of the delivery system to instruct patients on the correct use of the pen. The date of first injection should also be written on the outer carton of Terrosa.

Contraindications: Hypersensitivity to the active substance or to any of the excipients, pregnancy and breast-feeding, pre-existing hypercalcaemia, severe renal impairment, metabolic bone diseases (including hyperparathyroidism and Paget's disease of the bone) other than primary osteoporosis or glucocorticoid-induced osteoporosis, unexplained elevations of alkaline phosphatase, prior external beam or implant radiation therapy to the skeleton, patients with skeletal malignancies or bone metastases.

Warnings and precautions: If blood samples for serum calcium measurements are taken, this should be done at least 16 hours after the most recent teriparatide injection. Teriparatide may cause small increases in urinary calcium excretion. Use with caution in patients with active or recent urolithiasis. Isolated episodes of transient orthostatic hypotension have been observed within the first several doses and typically within 4 hours of dosing, resolving spontaneously and within a few minutes to a few hours. Episodes were relieved by placing subjects in a reclining position and did not preclude continued treatment. Caution in patients with moderate renal impairment. Experience in the younger adult population, including premenopausal women, is limited. Women of childbearing potential should use effective methods of contraception during use of teriparatide. If pregnancy occurs, teriparatide should be discontinued. Animal studies indicate an increased incidence of osteosarcoma with long-term administration of teriparatide, therefore the recommended treatment time of 24 months should not be exceeded. Batch (Lot) number of each cartridge and the date of its first injection should be recorded by the patient on a calendar.

Interactions: Case reports suggest that hypercalcaemia may predispose patients to digitalis toxicity. Because teriparatide transiently increases serum calcium, teriparatide should be used with caution in patients taking digitalis. Co-administration of raloxifene or hormone replacement therapy did not alter the effect of teriparatide on serum or urine calcium or on clinical adverse events.

Fertility, Pregnancy and Lactation: Women of childbearing potential should use effective methods of contraception during use of teriparatide. If pregnancy occurs, Terrosa should be discontinued. Terrosa is contraindicated for use during pregnancy and breast-feeding. It is not known whether teriparatide is excreted

in human milk. Studies in rabbits have shown reproductive toxicity. The effect of teriparatide on human foetal development has not been studied. The potential risk for humans is unknown.

Undesirable effects: The most commonly reported adverse reactions in patients treated with teriparatide are nausea, pain in limb, headache and dizziness.

Common: Anaemia, hypercholesterolaemia, depression, sciatica, syncope, vertigo, palpitations, hypotension, dyspnoea, vomiting, hiatus hernia, gastro-oesophageal reflex disease, sweating increased, muscle cramps, fatigue, chest pain, asthenia, mild and transient injection site events including pain, swelling erythema, localised bruising, pruritis and minor bleeding at injection site.

Serious reactions (uncommon and rare): tachycardia, emphysema, urinary incontinence, nephrolithiasis, cardiac murmur, anaphylaxis, hypercalcaemia, renal failure impairment, Possible allergic events soon after injection: acute dyspnoea, oro/facial oedema, generalised urticaria, chest pain, oedema (mainly peripheral

Consult SmPC in relation to other adverse events.

Legal category: POM

Pack size and NHS price: TERROSA 20mcg/80microlitres injection x 1 cartridge pack £239.25, Terrosa 20mcg/80microlitres injection x 3 cartridge pack £717.75, Terrosa 20mcg/80microlitres injection x starter pack (1 pen and 1 cartridge) £239.25.

Marketing Authorization Number: EU/1/16/1159/001 [1 cartridge], EU/1/16/1159/002 [3 cartridges], EU/1/16/1159/003 [cartridge and pen pack]

Marketing Authorization Holder: Gedeon Richter Plc. Gyömrői út 19-21. 1103 Budapest, Hungary.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store Adverse events should also be reported to Gedeon Richter (UK) Ltd on +44 (0) 207 604 8806 or drugsafety.uk@gedeonrichter.eu