CAMCEVI®
(leuprolide) 42mg
prolonged-release
suspension for injection

Leuprorelin
Remastered

Prescribing Information

CAMCEVI 42 mg prolonged-release suspension for injection

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

Presentation: Each pre-filled syringe with prolonged-release suspension for injection contains leuprorelin mesilate equivalent to 42 mg leuprorelin.

Indications: Metastatic prostate cancer; locally advanced prostate cancer, as an alternative to surgical castration; as an adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer; as an adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression; as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.

Dosage and Administration: *Adult prostate cancer patients:* CAMCEVI should be administered under the direction of a healthcare professional having available the appropriate expertise for monitoring the response to treatment. CAMCEVI is administered as a single subcutaneous injection every six months. The injected suspension forms a solid medicinal product delivery depot and provides continuous release of leuprorelin over a six-month period. As a rule, therapy of advanced prostate cancer with leuprorelin entails long-term treatment and therapy should not be discontinued when remission or improvement occurs. Leuprorelin may be used as neoadjuvant or adjuvant therapy in combination with radiotherapy in high-risk localised and locally advanced prostate cancer. Response to leuprorelin should be monitored by clinical parameters and by measuring prostate specific antigen (PSA) serum levels. Clinical studies have shown that testosterone levels increased during the first 3 days of treatment in the majority of non-orchiectomised patients and then decreased to below medical castration levels within 3 to 4 weeks. Once attained, castrate levels were maintained as long as leuprorelin therapy continued (<1% testosterone breakthroughs). In case the patient's response appears to be sub-optimal, it should be confirmed that serum testosterone levels have reached or are remaining at castrate levels. Patients treated with GnRH analogues for prostate cancer, treatment is usually continued upon development of castrate-resistant prostate cancer. Reference should be made to relevant guidelines. *Special populations: Renal/hepatic impairment:* No clinical studies were performed. *Paediatric population:* The safety and efficacy in children aged 0 to 18 years have not been established. No data are available. *Method of administration:* Subcutaneous use only, administered by healthcare professionals who are familiar with these procedures. Intra-arterial or intravenous injection, respectively, has to be strictly avoided. As with other medicinal products administered by subcutaneous injection, the injection site should be varied periodically.

Contraindications: In women and paediatric patients; hypersensitivity to the active substance, to other GnRH agonists or to any of the excipients; patients who previously underwent orchiectomy (as with other GnRH agonists, leuprorelin does not result in further decrease of serum testosterone in case of surgical castration); as sole treatment in prostate cancer patients with spinal cord compression or evidence of spinal metastases.

Warnings and Precautions: *Androgen deprivation therapy may prolong the QT interval:* Patients with a history of or risk factors for QT prolongation and patients receiving concomitant medicinal products that might prolong the QT interval physicians should assess the benefit/risk ratio including the potential for Torsade de pointes prior to initiating leuprorelin. Periodic monitoring of electrocardiograms and electrolytes should be considered. *Cardiovascular diseases:* Increased risk of developing myocardial infarction, sudden cardiac death and stroke has been reported in association with use of GnRH agonists in men. The risk appears low based on the reported odds ratios, and should be evaluated carefully along with cardiovascular risk factors when determining a treatment for patients with prostate cancer. Patients receiving GnRH agonists should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed according to current clinical practice. *Transient testosterone flare:* Leuprorelin, like other GnRH agonists, causes a transient increase in serum concentrations of testosterone, dihydrotestosterone and acid phosphatase during the first week of treatment. Patients may experience worsening of symptoms or onset of new symptoms, including bone pain, neuropathy, haematuria, or ureteral or bladder outlet obstruction. These symptoms usually subside on continuation of therapy. Additional administration of an appropriate antiandrogen should be considered beginning 3 days prior to leuprorelin therapy and continuing for the first two to three weeks of treatment. This has been reported to prevent the sequelae of an initial rise in serum testosterone. Following surgical castration, leuprorelin does not lead to a further decrease in serum testosterone levels in male patients. *Bone density:* Decreased bone density has been reported in the medical literature in men who have had orchiectomy or who have been treated with GnRH agonists. Antiandrogen therapy significantly increases the risk for fractures owing to osteoporosis. Only limited data is available on this issue. Fractures owing to osteoporosis were observed in 5% of patients following 22 months of pharmacological androgen deprivation therapy and in 4% of patients following 5 to 10 years of treatment. The risk for fractures owing to osteoporosis is generally higher than the risk for pathological fractures. Apart from long lasting testosterone deficiency, increased age, smoking and consumption of alcoholic beverages, obesity and insufficient exercise may have an influence on the development of osteoporosis. *Pituitary apoplexy:* During post-marketing surveillance, rare cases of pituitary apoplexy (a clinical syndrome secondary to infarction of the pituitary gland) have been reported after the administration of GnRH agonists, with a majority occurring within 2 weeks of the first dose, and some within the first hour. In these cases, pituitary apoplexy was presented as sudden headache, vomiting, visual changes, ophthalmoplegia, altered mental status, and sometimes cardiovascular collapse. Immediate medical attention is required. *Hyperglycaemia and diabetes:* Hyperglycaemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Hyperglycaemia may represent development of diabetes mellitus or worsening of glycaemic control in patients with diabetes. Blood glucose and/or glycosylated haemoglobin (HbA1c) should be monitored periodically in patients receiving a GnRH agonist and patients should be managed with current practice for treatment of hyperglycaemia or diabetes. Metabolic changes associated with GnRH agonist may also include fatty liver disease. *Convulsions:* Post-marketing reports of convulsions have been observed in patients on leuprorelin with or without a history of predisposing factors. Convulsions are to be managed according to the current clinical practice. *Idiopathic intracranial hypertension (pseudotumor cerebri):* Has been reported. Patients should be warned for signs and symptoms, including severe or recurrent headache, vision disturbances and tinnitus. If idiopathic intracranial hypertension occurs, discontinuation of leuprorelin should be considered. *Severe cutaneous adverse reactions (SCARs):* Including Stevens-Johnson syndrome (SJS), and Toxic epidermal necrolysis (TEN) which can be life-threatening or fatal, have been reported in association with treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for severe skin reactions. If signs and symptoms suggestive of these reactions appear, leuprorelin should be withdrawn immediately and an alternative treatment considered (as appropriate). *Other events:* Cases of ureteral obstruction and spinal cord compression, which may contribute to paralysis with or without fatal complications, have been reported with GnRH agonists. If spinal cord compression or renal impairment develops, standard treatment of these complications should be instituted. Patients with vertebral and/or brain metastases as well as patients with urinary tract obstruction should be closely monitored during the first few weeks of therapy. *Depression:* Increased risk of incident depression (which may be severe) in patients undergoing treatment. Patients should be informed and monitored accordingly and treated as appropriate if symptoms occur. *Effects on ability to drive and use machines:* The administration of this medicinal product can cause fatigue, dizziness and visual disturbances. Patients should be advised not to drive or operate machinery if these adverse reactions occur.

Fertility, Pregnancy & Lactation: Contraindicated in women. Based on findings in animals and mechanism of action, leuprorelin may impair fertility in males of reproductive potential.

Adverse Events include:

Adverse events which could be considered serious: Urinary tract infection; anaemia; aggravated diabetes mellitus; depression; headache; hypoaesthesia; idiopathic intracranial hypertension (pseudotumor cerebri); QT prolongation; myocardial infarction; hypertension; hypotension; syncope; collapse; dyspnoea; interstitial lung disease; gastroenteritis/colitis; erythema; toxic skin eruption; Stevens-Johnson syndrome/Toxic Epidermal Necrolysis (SJS/TEN); erythema multiforme; urinary retention; erectile dysfunction; pyrexia; injection site necrosis; pulmonary embolism; thrombocytopenia; pituitary apoplexy; anaphylactic/anaphylactoid reactions.

Other Very Common adverse events: Hot flushes; ecchymoses; fatigue; injection site burning; injection site paraesthesia; transient local irritation at the site of injection.

Other Common adverse events: Haematology changes; nausea; diarrhoea; pruritus; night sweats; arthralgia; limb pain; myalgia; rigors; weakness; urinary infrequency, difficulty in micturition, dysuria, nocturia, oliguria; breast tenderness; testicular atrophy; testicular pain; infertility; breast hypertrophy; reduced penis size; malaise; injection site pain; injection site bruising; injection site stinging; increased blood creatinine phosphokinase; prolonged coagulation time; nasopharyngitis. See SmPC for details of other adverse events.

Presentation and Price: 1 x 42 mg pre-filled syringe = £404.00

Legal Category: POM

Further information is available from: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS.

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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 Accord-UK LTD on 01271 385257 or email medinfo@accord-healthcare.com.

Intended for UK Healthcare Professionals only.

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