Leuprorelin 3.75mg Therapy- 28day

INDICATIONS FOR USE:

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Regimen Code</th>
<th>Reimbursement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of prostatic carcinoma for which a suppression of testosterone is indicated</td>
<td>C61</td>
<td>00494a</td>
<td>CDS</td>
</tr>
</tbody>
</table>

TREATMENT:
Leuprorelin 3.75mg is administered as a single subcutaneous or intramuscular injection once every 28 days until disease progression or unacceptable toxicity develops.

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Diluent &amp; Rate</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Leuprorelin</td>
<td>3.75mg</td>
<td>SC or IM</td>
<td>n/a</td>
<td>Every 4 weeks</td>
</tr>
</tbody>
</table>

ELIGIBILITY:
- Indications as above

EXCLUSIONS:
- Hypersensitivity to leuprorelin or any of the excipients
- As sole treatment in prostate cancer patients with spinal cord compression or evidence of spinal metastases

PRESCRIPTIVE AUTHORITY:
The treatment plan must be initiated by a Consultant with expertise in the treatment of prostate carcinoma.

TESTS:
Baseline tests:
- FBC, renal and liver profile
- Bone profile
- Blood glucose

Regular tests:
- FBC, renal and liver profile as clinically indicated
- Blood glucose and bone profile as clinically indicated

Disease monitoring:
Disease monitoring should be in line with the patient’s treatment plan and any other test/s as directed by the supervising Consultant.
DOSE MODIFICATIONS:
- No recommended dose modifications.

Table 1: Dose modification of leuprolrelin in renal and hepatic impairment

<table>
<thead>
<tr>
<th>Renal Impairment</th>
<th>Hepatic Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No dose modification necessary</td>
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</tr>
</tbody>
</table>

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Minimal (Refer to local policy).

PREMEDICATIONS: None

OTHER SUPPORTIVE CARE:
Calcium and vitamin D supplementation (Refer to local policy).

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS
The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- **Transient testosterone flare**: Leuprolrelin acetate, like other gonadotrophin-releasing hormone (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 leuprolrelin 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.

- **Bone Mineral Density**: The use of LHRH agonists may cause reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with an LHRH agonist may reduce bone mineral loss. Particular caution is necessary in patients with additional risk factors for osteoporosis (e.g. chronic alcohol abusers, smokers, long-term therapy with anticonvulsants or corticosteroids, family history of osteoporosis).

- **Glucose Tolerance**: Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Hyperglycemia may represent development of diabetes mellitus or worsening of glycemic control in patients with diabetes. Monitor blood glucose and/or glycosylated hemoglobin (HbA1c) periodically in patients receiving a GnRH agonist and manage with current practice for treatment of hyperglycemia or diabetes.

DRUG INTERACTIONS:
- Since androgen deprivation treatment may prolong the QT interval, the concomitant use of leuprolrelin with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes should be carefully evaluated.
- Current drug interaction databases should be consulted for more information.
NCCP Chemotherapy Regimen

ATC CODE:
Leuprorelin       L02AE02

REFERENCES:

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Amendment</th>
<th>Approved By</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>30/05/2018</td>
<td></td>
<td>Prof Maccon Keane</td>
</tr>
<tr>
<td>2</td>
<td>10/06/2020</td>
<td>Regimen review</td>
<td>Prof Maccon Keane</td>
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Comments and feedback welcome at oncologydrugs@cancercontrol.ie.