### 5-FU 225mg/m²/day and Radiotherapy (RT)-Continuous infusion (7 day)

**INDICATIONS FOR USE:**

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Regimen Code</th>
<th>*Reimbursement Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of locally advanced rectal cancer</td>
<td>C20</td>
<td>00421a</td>
<td></td>
</tr>
</tbody>
</table>

*If a reimbursement indicator (e.g. ODMS, CDS) is not defined, the drug and its detailed indication have not gone through the formal reimbursement process as legislated for in the Health (Pricing and Supply of Medical Goods) Act 2013.

**TREATMENT:**

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patient's individual clinical circumstances.

5-FU is administered by continuous infusion with concurrent radiotherapy for 6 weeks.

The 5FU infusor pump should be changed every 7 days.

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route and Method of Administration</th>
<th>Diluent &amp; Rate</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-7</td>
<td>5-FU</td>
<td>225mg/m²/day</td>
<td>Continuous IV infusion over 7 days</td>
<td>Infusor pump</td>
<td>For duration of radiotherapy (6 weeks)</td>
</tr>
</tbody>
</table>

**ELIGIBLITY:**

- Indications as above
- ECOG status 0-2

**EXCLUSIONS:**

- Hypersensitivity to 5-FU or any of the excipients
- Pregnancy
- Breast Feeding

**PRESCRIPTIVE AUTHORITY:**

The treatment plan must be initiated by a Consultant Medical Oncologist.

**TESTS:**

**Baseline tests:**

- FBC, U&E, LFTs

**Regular tests:**

- FBC, U&E, LFTs weekly throughout treatment

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The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician, and is subject to HSE’s terms of use available [here](http://www.hse.ie/eng/Disclaimer).

This information is valid only on the day of printing, for any updates please check [www.hse.ie/NCCPchemoregimens](http://www.hse.ie/NCCPchemoregimens)
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:
- Any dose modification should be discussed with a Consultant

Haematological:

### Table 1: Dose Modification for Haematological toxicity

<table>
<thead>
<tr>
<th>ANC (x 10^9/L) (on day of chemotherapy)</th>
<th>Platelets (x 10^9/L) (at any stage during cycle)</th>
<th>Dose Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥1</td>
<td>≥100</td>
<td>100% Dose</td>
</tr>
<tr>
<td>0.5 - 0.99</td>
<td>50-99</td>
<td>Delay treatment until recovery</td>
</tr>
<tr>
<td>&lt;0.5</td>
<td>&lt;50</td>
<td>Delay treatment until recovery and consider reducing fluorouracil by 25% for subsequent cycles</td>
</tr>
</tbody>
</table>

Renal and Hepatic Impairment:

### Table 2: Dose Modification for Renal and Hepatic Impairment

<table>
<thead>
<tr>
<th>Renal Impairment</th>
<th>Hepatic Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consider dose reduction in severe renal impairment only</td>
<td>Clinical decision. Moderate hepatic impairment; reduce initial dose by 1/3. Severe hepatic impairment, reduce initial dose by 1/2.</td>
</tr>
</tbody>
</table>

**SUPPORTIVE CARE:***

**EMETOGENIC POTENTIAL:** Low (Refer to local policy).

**PREMEDICATIONS:** Not required

**OTHER SUPPORTIVE CARE:** No specific recommendations

**ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS**

This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions. The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- **Myocardial ischaemia and angina:** Cardiotoxicity is a serious complication during treatment with fluorouracil. Patients, especially those with a prior history of cardiac disease or other risk factors, treated with fluorouracil, should be carefully monitored during therapy.

- **Dihydropyrimidine dehydrogenase (DPD) deficiency:** Rare, life-threatening toxicities such as stomatitis, mucositis, neutropenia, neurotoxicity and diarrhoea have been reported following administration of fluoropyrimidines (e.g. fluorouracil and capecitabine). Severe unexplained toxicities require investigation prior to continuing with treatment.

**DRUG INTERACTIONS:**

- Marked elevations of prothrombin time and INR have been reported in patients stabilized on warfarin therapy following initiation of fluorouracil regimes.
• Concurrent administration of fluorouracil and phenytoin may result in increased serum levels of phenytoin
• Caution should be taken when using fluorouracil in conjunction with medications which may affect dihydropyrimidine dehydrogenase activity.
• Current drug interaction databases should be consulted for more information.

ATC CODE:
5-FU - L01BC02

REFERENCES:

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

1 ODMS – Oncology Drug Management System
CDS – Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS community drug schemes
Further details on the Cancer Drug Management Programme is available at; http://www.hse.ie/eng/services/list/5/cancer/profinfolmedonc/