Ondansetron is a generic medicine, with years of experience worldwide. In New Zealand, the United Kingdom and the United States ondansetron is indicated for nausea and vomiting due to cytotoxic chemotherapy or radiotherapy, and surgery.\(^1,2\) There is some evidence to support use for other conditions associated with nausea and vomiting such as acute gastroenteritis.\(^3\) Ondansetron has been used successfully for the management of diarrhoea with irritable bowel syndrome,\(^4\) and there is some evidence to suggest it may be effective for alcoholism in selected patients.\(^5\)

**Note:** If the indication is considered *experimental*, written consent from the patient needs to be obtained.\(^6\) If a medicine is used ‘off-label’ for a *commonly* used indication, obtaining consent may not be considered necessary; this is at the discretion of the prescriber.\(^6\)

**TAKE CARE, QT INTERVAL PROLONGATION HAS BEEN REPORTED**

Ondansetron prolongs the QT interval in a dose-dependent manner. This can lead to abnormal and potentially fatal heart rhythms, including Torsade de Pointes.\(^7\) Advise patients to immediately report irregular heartbeat, shortness of breath, dizziness, or fainting while taking ondansetron.

Patients at particular risk for developing Torsade de Pointes include those with underlying heart conditions, such as congenital long QT syndrome, congestive heart failure, those who are predisposed to hypokalaemia or hypomagnesaemia, and those taking other medications that lead to QT prolongation or electrolyte abnormalities.\(^7\)

**UNDERSTAND SAFE USE WITH CHILDREN AND ADOLESCENTS**

The use of oral ondansetron for children and adolescents is supported due to extensive evidence from its use in oncology and in a range of other settings including gastroenteritis. Ondansetron is considered safer than other antiemetics in children and adolescents, where the risk of dystonic reaction is higher.

Although acute gastroenteritis is usually self-limiting, and the use of antiemetics is often not necessary, ondansetron has demonstrated benefit in reducing the number of episodes of gastroenteritis-associated vomiting in children and adolescents.\(^3,8\) If children are dehydrated, ondansetron can decrease the necessity of intravenous fluid therapy and potential hospitalisation\(^3\) with fewer adverse effects than the older generation of antiemetics.\(^8\)

The underlying cause of vomiting should always be investigated. A single dose of oral ondansetron given to children with mild to moderate dehydration can control vomiting and is often sufficient to allow oral rehydration therapy.\(^7\) Prescribing additional doses is often not required for gastroenteritis.

**Table 2: Recommended single dose for children over 12 months**

<table>
<thead>
<tr>
<th>Weight</th>
<th>Ondansetron tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;15kg</td>
<td>2mg</td>
</tr>
<tr>
<td>&gt;15kg</td>
<td>4mg</td>
</tr>
</tbody>
</table>

**Note:** The oral dissolving (orodispersible) tablet formulation or wafer is to be placed on top of the tongue, allowed to disperse, then swallowed.\(^10\)

» continued
INFORM PREGNANT WOMEN THAT SAFETY HAS NOT BEEN FULLY ESTABLISHED

Ondansetron is used for hyperemesis gravidum due to its efficacy, but safety in pregnancy has not been fully established. Constipation is commonly reported and can exacerbate symptoms of bloating and abdominal discomfort during pregnancy. Ondansetron is currently classified pregnancy category B1*; it is essential that the patient is fully aware there is lack of robust safety data before prescribing. Any antiemetic should be used at the lowest effective dose for the shortest possible time during pregnancy.

*Category B1*

Drugs which have been taken by a limited number of pregnant women without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals show no evidence of an increased occurrence of foetal damage.

Note: Animal studies are not always predictive of human response.

EXPLAIN THAT HEADACHE, CONSTIPATION AND DIZZINESS ARE COMMON

The most frequent adverse effects associated with ondansetron are headaches, constipation and flushing or a sensation of warmth. Take special care if patients have symptomatic hypotension or if they are predisposed to constipation (eg from opiate use).

The effect of ondansetron may be reduced if it is taken with phenytoin, carbamazepine and rifampicin. Ondansetron may reduce the analgesic effects of tramadol, and this combination may increase the risk of serotonin syndrome.

Serotonin syndrome can occur with ondansetron, especially if it is used in combination with other serotonergic medicines. If these combinations cannot be avoided, observe closely for symptoms (fever, tremors, agitation), and discontinue if serotonin syndrome is suspected.

The dose of ondansetron does not need to be adjusted for patients with renal impairment. If patients have moderate to severe hepatic impairment, the clearance of ondansetron is significantly reduced; the total daily dose should not exceed 8mg in these cases.

REFERENCES


ACKNOWLEDGEMENTS

We wish to thank Michael Shepherd, Clinical Director of the Emergency Department, Starship Children’s Hospital, Auckland for his valuable contribution to this bulletin.

For further information on other high-risk medicines visit our website at: www.saferx.co.nz

No: 0182-01-086, Issued June 2016, Review June 2019

DISCLAIMER: This information is provided to assist primary care health professionals with the use of prescribed medicines. Users of this information must always consider current best practice and use their clinical judgement with each patient. This information is not a substitute for individual clinical decision making. Issued by the Quality Use of Medicines Team at Waitemata District Health Board email: feedback@saferx.co.nz