



ONDANSETRON - SAFE PRESCRIBING - RELIEVE THE HEAVE

- TAKE CARE, QT INTERVAL PROLONGATION HAS BEEN REPORTED
- UNDERSTAND SAFE USE WITH CHILDREN AND ADOLESCENTS
- INFORM PREGNANT WOMEN THAT SAFETY HAS NOT BEEN FULLY ESTABLISHED
- ▶ EXPLAIN THAT HEADACHE, CONSTIPATION AND DIZZINESS ARE COMMON

Ondansetron is a generic medicine, with years of experience worldwide and is indicated for nausea and vomiting due to cytotoxic chemotherapy or radiotherapy, and surgery.

There is some evidence to support use for other conditions associated with nausea and vomiting such as acute gastroenteritis.

Note: If the indication is considered *experimental*, written consent from the patient needs to be obtained. 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.

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. 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 congenital long QT syndrome, congestive heart failure, those who are predisposed to hypokalaemia or hypomagnesia, and those taking other medications that lead to QT prolongation or electrolyte abnormalities.

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. Although acute gastroenteritis is usually self-limiting, and antiemetics are not usually necessary, 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. Prescribing additional doses is often not required, and the underlying cause of vomiting should always be investigated.

Table 2: Recommended single dose for children over 12 months

Weight	Orodispersible ondansetron tablet
<15kg	2mg
>15kg	4mg

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

INFORM PREGNANT WOMEN THAT SAFETY HAS NOT BEEN FULLY ESTABLISHED

Ondansetron is used for hyperemesis gravidium due to its efficacy, but safety in pregnancy has not been fully established. Constipation is commonly reported and can lead to 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.

🛏 continued





ONDANSETRON

EXPLAIN THAT HEADACHE, CONSTIPATION AND DIZZINESS ARE COMMON

The most frequent adverse effects 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 if ondansetron is used in combination with other serotonergic medicines. If these combinations cannot be avoided, observe for symptoms (fever, tremors, agitation), and discontinue if it is suspected.

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

KEY REFERENCES

- Rex Medical New Zealand Datasheet Onrex tablets (ondansetron hydrochloride dihydrate tablets 4mg and 8mg) 01-03-12. <u>www.medsafe.govt.nz/profs/datasheet/o/Onrextab.pdf</u> (Accessed 17-11-15)
- Healthpoint pathways. Paediatric management of diarrhoea and vomiting caused by gastroenteritis. Adapted from POAC guidelines. <u>www.healthpointpathways.co.nz/</u> <u>northern/paediatric-a-z/gastroenteritis-paediatric-1/</u> (Accessed 16-02-16)
- The New Zealand Formulary, ondansetron. <u>http://nzf.org.nz/nzf_2392</u> (Accessed 13-11-15)

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.

CLICK HERE FOR FURTHER INFORMATION ON ONDANSETRON AND A FULL REFERENCE LIST

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