Pfizer Healthcare Ireland
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Citywest Business Campus, Dublin 24.
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Internal Ref: PH2391190406

Dear Healthcare Professional,

Re: Zyvox 2mg/ml Solution for Infusion, Zyvox 400mg FC Tablet, Zyvox 600mg FC Tablet, & Zyvox 100mg/5ml Granules for Oral Solution. PA936/11/1, 2, 3 & 4.
Marketing Authorisation Holder, Pharmacia Ireland Ltd.

The risks associated with long-term use

Further to discussion with the Irish Medicine Board, Pfizer wishes to advise you about important safety information that will be added to the Summary of Product Characteristics (SPC) for Zyvox in response to information received through post marketing surveillance.

Rare cases of peripheral neuropathy and/or optic neuropathy, sometimes progressing to loss of vision, anaemia that requires blood transfusion, and lactic acidosis have been reported in patients treated with Zyvox. These reactions have primarily occurred in patients treated for longer than the maximum recommended duration of 28 days

We estimate that since its launch in 2000, over one million patients have been treated with linezolid worldwide. While it is not possible to establish an incidence rate for these adverse reactions due to the inherent limitations of spontaneous adverse event reporting, such cases have been reported rarely. Of the optic neuropathy cases with known outcomes, three-quarters reported recovery. A quarter of cases progressed to vision loss and of those with known outcomes, half reported recovery. Of the peripheral neuropathy cases with known outcomes, a third reported complete or ongoing recovery.

We would like to remind you that Zyvox is indicated for the treatment of nosocomial pneumonia, community-acquired pneumonia, and complicated skin and soft tissue infections, when known or suspected to be caused by susceptible gram-positive bacteria. Treatment should only be initiated in a hospital environment and after consultation with a relevant specialist. The recommended treatment duration for these conditions is 10-14 consecutive days, with a maximum treatment duration of 28 days. The safety and efficacy of linezolid have **not** been established when administered for periods longer than 28 days. Please refer to the SPC (enclosed) for full prescribing information.

Health care professionals are advised to:

Optic neuropathy

- Direct patients to immediately report any symptoms of visual impairment, including changes in visual acuity, changes in colour vision, blurred vision or visual field defect.
- Ensure that any patient experiencing new visual symptoms undergoes prompt evaluation, with referral to an ophthalmologist as necessary.
- Regularly monitor the visual function of all patients who may require treatment for longer than 28 days due to an exceptional medical need.

Peripheral neuropathy

- Direct patients to immediately report any symptoms of neuropathy, including hypoaesthesia and paraesthesia.

Myelosuppression

- Direct patients to report any symptoms of anaemia or thrombocytopenia.
- Monitor complete blood counts weekly in all patients, irrespective of their baseline blood count and treatment duration.
- Stop treatment with Zyvox if significant myelosuppression occurs. If continued treatment is considered essential, blood counts should be intensively monitored and appropriate management strategies should be implemented.

Lactic acidosis

- Direct patients to report any symptoms of lactic acidosis, including recurrent nausea or vomiting, abdominal pain, or hyperventilation. Such patients should receive immediate medical attention.

If peripheral neuropathy, optic neuropathy, significant myelosuppression or lactic acidosis occurs, the benefits of continued use of Zyvox should be balanced against the potential risks to the patient.

If you have any enquiries or want additional information concerning this important safety information, please contact Pfizer UK Ltd., on freephone 1800 633 363 and ask for Medical Information.

Please report any cases of suspected adverse reactions in association with the use of Zyvox to Pfizer UK Ltd., and the Irish Medicine Board in the usual way. The contact details for Pfizer are Pfizer UK Ltd., Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK or by using the freephone 1800 633 363 and asking for the Drug Safety Group.

Yours sincerely,

John Farrell

Dr. John Farrell
Medical Director.