

In all cases increasing improvement was apparent over the dosage range 25-100mg.⁵⁻⁸

Reduced responses were seen in diabetic men with ED and men with ED post radical prostatectomy. Improved erections were only reported in 50-60% and 40-50% of these patients respectively.^{7,8}

Patients enrolled in these randomised, double-blind, placebo-controlled trials were entered into open label extension studies. The outcome of these studies is not yet available.⁷

Adverse Effects

Adverse events seen in clinical trials were predominantly transient, mild or moderate in nature and dose related. Only 2.5% of patients withdrew from sildenafil treatment due to an adverse event compared to 2.3% on placebo. The majority of adverse events seen with sildenafil related to its known pharmacological properties; vasodilatation (including headache, flushing, nasal congestion), gastrointestinal events (dyspepsia) and visual effects (abnormal vision).^{1,5-8}

The adverse effects on vision, reported as light sensitivity and bluish vision lasting from a few minutes to a few hours, have been recorded particularly at high doses. No effects on other objective measures of visual function, e.g. visual acuity, have been reported. Any long-term consequences of this side effect are not known.^{1,8,9}

No clinically significant changes in blood pressure, heart rate or ECG and no increase in the development of serious cardiovascular events were seen with sildenafil in clinical trials. Sildenafil has not been shown to have a direct effect on platelet aggregation or an effect on sperm motility or morphology. Priapism has been reported in post marketing surveillance studies.^{1,8,9}

During post-marketing surveillance, serious adverse events including MI, angina, sudden cardiac death and ventricular arrhythmia have been reported in temporal association with sildenafil.¹

Costs

Sildenafil is available in three tablet strengths; 25mg, 50mg & 100mg. These are provided in packs of 4 and 8 tablets. The current basic price per tablet is £4.15 for 25mg, £4.84 for 50mg and £5.88 for a 100mg tablet.

Summary

ED is currently an under reported condition. The launch of sildenafil is anticipated to increase the number of patients presenting with ED. For each patient a careful evaluation

of the potential underlying cause of the condition should be undertaken, before sildenafil treatment is considered.

Sildenafil has been evaluated in approximately 4,000 men with ED in 21 randomised double-blind, placebo-controlled trials over periods of up to 6 months. Sildenafil 25 - 100mg was effective in approximately 75% of patients, although lower responses were apparent in diabetic men and those with ED following a radical prostatectomy.

Adverse events seen in clinical trials were generally transient and predictable. Visual abnormalities were noted particularly at doses above 100mg. There are concerns regarding the possible long-term consequences of this adverse effect. A temporal association with serious adverse events, including MI, has been reported. Sildenafil should not be co-administered with nitrates since large and sudden drops in BP have occurred.

Careful targeting of the drug to those who require treatment will be essential since it is anticipated that there will be a broad market for the drug in men with perceived reduced sexual functioning in the hope of improving performance. The Department of Health has issued guidance advising against the prescribing of sildenafil (except in exceptional circumstances) at NHS expense.

References

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SS00/18

THIS SUMMARY SHEET REPLACES SS99/15 WHICH SHOULD BE REMOVED AND DESTROYED

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