

Recommendations:

- Amendments to the Product Information

→ SmPC

Changes (based in current SmPC for Seroxat) marked blue

→ Section 4.4 Special Warnings and Special Precautions for use

Diabetes

In patients with diabetes, treatment with an SSRI may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted. Additionally, there have been studies suggesting that an increase in blood glucose levels may occur when paroxetine and pravastatin are co-administered. (see section 4.5)

→ Section 4.5 Interactions with other medicinal products and other forms of interaction

Pravastatin

An interaction between paroxetine and pravastatin has been observed in studies suggesting that

co-administration of paroxetine and pravastatin may lead to an increase in blood glucose levels. Patients with diabetes mellitus receiving both paroxetine and pravastatin may require dosage adjustment of oral hypoglycaemic agents and/or insulin (see section 4.4).

→ Section 4.8 Undesirable Effects

Immune system disorders

Very rare: severe and potentially fatal allergic reactions (including anaphylactoid reactions, ~~urticaria~~ and angioedema).

Metabolism and nutrition disorders

Uncommon: Altered glycaemic control has been reported in diabetic patients (see section 4.4).

Skin and subcutaneous tissue disorders

Common: sweating.

Uncommon: skin rashes, pruritus

Very rare: severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis), urticaria, photosensitivity reactions.

→ Package leaflet

Changes (based on current PL for Seroxat) marked blue

Section 2 What you need to know before you take 'Tradename'

Taking other medicines and 'TRADENAME'

Some medicines can affect the way 'TRADENAME' works, or make it more likely that you'll have side effects. 'TRADENAME' can also affect the way some other medicines work. These include:

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- Metoprolol, a beta-blocker used to treat **high blood pressure** and **heart problems**
- **Pravastatin**, used to treat **high cholesterol**

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Section 4 Possible side effects

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Very rare side effects, likely to affect up to 1 in every 10,000 people:

- **Allergic reactions, which may be severe** to 'TRADENAME'.
If you develop a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, start to itch or have difficulty breathing (**shortness of breath**) or swallowing **and feel weak or lightheaded resulting in collapse or loss of consciousness**, **contact your doctor or go to a hospital straight away.**

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Uncommon side effects, likely to affect up to 1 in every 100 people:

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- An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence)
- **If you are a diabetic patient you may notice a loss of control of your blood sugar levels whilst taking 'TRADENAME'. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.**

Agreed topics for close monitoring and review in the next PSUR are:

The following adverse events should be closely monitored by the MAHs having marketing authorisation for products containing paroxetine:

- Paroxetine and pregnancy (including miscarriage)
- Migraine
- Alopecia
- Hyperacusis
- Hostility/aggression
- Reversible cerebral vasoconstriction syndrome
- Testicular carcinoma
- Glycaemic control in non-diabetic patients
- Intraventricular haemorrhage/neonatal haemorrhage and brain haemorrhage/stroke
- Persistent sexual dysfunction after the discontinuation of paroxetine