Use in the elderly:

Several hundred elderly patients have participated in clinical studies with Agrelocit. The pattern and incidence of adverse reactions in the elderly is similar to that in younger patients.

Use in hepatic Impairment:

There is insufficient clinical experience in patients with significant hepatic dysfunction and accordingly Agrelocit should not be used in such patients. Concomitant use in patients taking pimozide is contra-indicated (Interaction with other Medicaments and other Forms of Interaction). Agrelocit should not be used in children and adolescents under the age of 18 years with Major Depressive Disorder.

Monoamine oxidase Inhibitors:

Cases of serious and sometimes fatal reactions have been reported in patients receiving an SSRI in combination with a monoamine oxidase inhibitor (MAOI), including the selective MAOI selegiline and the reversible MAOI (RIMA) moclobemide and in patients who have recently discontinued an SSRI and have been started on a MAOI. Some cases presented with features resembling serotonin syndrome. Symptoms of a drug interaction with a MAOI include: hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, mental status changes that include confusion, irritability and extreme agitation progressing to delirium and coma. Agrelocit should not be used in combination with a MAOI. Agrelocit may be started 14 days after discontinuing treatment with an irreversible MAOI and at least one day after discontinuing treatment with the reversible MAOI (RIMA). At least 14 days should elapse after discontinuing Agrelocit treatment before starting a MAOI or RIMA.

Children aged less than six years

Agrelocit is not recommended in children under six years of age since safety and efficacy have not been established.

Use in children aged 6-17 years

Treatment should only be initiated by specialists. The safety and efficacy of Agrelocit has been established in pediatric OCD patients (aged 6-17). The administration of Agrelocit to pediatric OCD patients (aged 13-17) should commence at 50 mg/day. Therapy for pediatric OCD patients (aged 6-12) should commence at 25mg/day increasing to 50mg/day after 1 week. Subsequent doses may be increased in case of lack of response in 50mg/day increments up to 200mg/day as needed. However, the generally lower body weights of children compared to adults should be taken into consideration in advancing the dose from 50mg, in order to avoid excessive dosing. Given the 24 hour elimination half-life of sertraline, dose changes should not occur at intervals of less than 1 week. The efficacy and safety of Agrelocit in children and adolescents under the age of 18 years with Major Depressive Disorder have not been established. Controlled clinical studies failed to demonstrate efficacy and do not support the use of Agrelocit in the treatment of children and adolescents with Major Depressive Disorder (Contra-Indications and Undesirable effects).