Summary of prescribing information for ATZ50 tablets

Active Ingredient: Each film coated tablet of ATZ50 contains: Azathioprine I.P. 50 mg. **Indication:** For facilitating the survival and function of organ transplants. **Dosage:** dose required to prevent rejection and minimize toxicity will vary with individual patients; this necessitates careful management. Initial dose is usually 3 to 5 mg/kg daily, beginning at the time of transplant. Azathioprine is usually given as a single daily dose on the day of, and in a minority of cases 1 to 3 days before, transplantation. Dose reduction to maintenance levels of 1 to 3 mg/kg daily is usually possible. The dose of azathioprine should not be increased to toxic levels because of threatened rejection. Discontinuation may be necessary for severe hematologic or other toxicity, even if rejection of the homograft may be a consequence of drug withdrawal. **Contraindications:** hypersensitivity to azathioprine and any other ingredients of the tablets. **Warning and precautions:** increases risk of malignancy in humans. Azathioprine may decrease WBC: recent CBC should be available before starting azathioprine. Monitor for signs and symptoms of infection. Unexpected bruising or bleeding or other manifestations of bone marrow depression. Inherited deficiency of the enzyme thiopurine methyltransferase (TPMT): more likely to develop the myelosuppressive effect of azathioprine. This could be exacerbated by co-administration with drugs that inhibit TPMT, such as olsalazine, mesalazine or sulfasalazine. Decreased TPMT activity increases the risk of secondary leukaemias and myelodysplasia in individuals receiving 6-mercaptopurine (the active metabolite of azathioprine) in combination with other cytotoxics. **Pregnancy & Lactation:** Pregnancy: should not be given to patients who are pregnant or likely to become pregnant without careful assessment of risk versus benefit. Lactation: 6-Mercaptopurine (active metabolite of azathiprine) has been identified in the colostrum and breast-milk of women receiving azathioprine treatment. **Interaction:** Allopurinol/ oxipurinol/ thiopurinol: reduced conversion of biologically active 6-thioinosinic acid to biologically inactive 6-thiouric acid, dose of azathioprine should be reduced to one-quarter of the original dose. Neuromuscular blocking agents: potentiate the neuromuscular blockade produced by depolarising agents such as succinylcholine, reduce the blockade produced by non-depolarising agents such as tubocurarine. Warfarin: Inhibition of the anticoagulant effect of warfarin. Cytostatic/myelosuppressive agents: cytostatic drugs, or drugs which may have a myelosuppressive effect, such as penicillamine, should be avoided. Vaccines: atypical and potentially deleterious response to live vaccines and so the administration of live vaccines. Diminished response to killed vaccines is likely and such a response to hepatitis B vaccine has been observed when combined corticosteroids. Cimetidine and indomethacin: may have myelosuppressive effects. **Adverse reactions:** common viral, fungal and bacterial infections; Depression of bone marrow function; leucopenia, Thrombocytopenia, Nausea and vomiting. **Overdose:** Symptoms: Unexplained infection, ulceration of the throat, bruising and bleeding, bone marrow depression may be maximal after 9 to 14 days. These signs are more likely to be manifest following chronic overdosage, rather than after a single acute overdose. The immediate toxic effects of this overdose were nausea, vomiting and diarrhoea, followed by mild leucopenia and mild abnormalities in liver function. Treatment: There is no specific antidote. Gastric lavage has been used. Subsequent monitoring, including haematological monitoring, is necessary to allow prompt treatment of any adverse effects which may develop. The value of dialysis in patients who have taken an overdose of azathioprine is not known, though azathioprine is partially dialysable.

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It is recommended to refer full prescribing information before prescription.

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