Yaltormin SR Tablets (metformin hydrochloride prolonged release tablet)
Prescribing Information

PRESENTATION
White to off-white, capsule shaped prolonged release tablets containing 500mg, 750mg or 1000mg metformin hydrochloride.

INDICATIONS
Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. Yaltormin SR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.

DOSAGE AND ADMINISTRATION
Adults with normal renal function (GFR ≥90 mL/min): The usual starting dose is one 500mg tablet once daily. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. Higher dose tablets are intended for patients who are already treated with metformin tablets (prolonged or immediate release) – in this case dose should be equivalent to the daily dose of metformin up to a maximum dose of 1500 mg for the 750mg capsules or 2000mg for the 1000mg capsules given with the evening meal. In patients treated with metformin at a dose above 2000 mg daily, switching to Yaltormin SR is not recommended. If using with insulin, adjust insulin dosage on the basis of blood glucose measurements. Dose adjustment is necessary based on renal function (consult SmPC). Regular assessment of renal function is necessary in the elderly and those with renal impairment.

CONTRAINDICATIONS
Hypersensitivity to metformin or any excipients. Any type of acute metabolic acidosis. Diabetic pre-coma. Severe renal failure (GFR <30mL/min). Acute conditions with the potential to alter renal function e.g. dehydration, severe infection, shock. Disease which may cause tissue hypoxia e.g. decompensated heart failure, respiratory failure, recent myocardial infarction, shock. Hepatic insufficiency, acute alcohol intoxication, alcoholism.

SPECIAL WARNINGS AND PRECAUTIONS
Lactic acidosis, a very rare, but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. If suspected the patient should stop taking metformin and seek immediate medical attention. In cases of dehydration metformin should be temporarily discontinued. Initiate products that can acutely impair renal function with caution. GFR should be assessed before treatment initiation and regularly thereafter. Metformin must be discontinued at the time of surgery with general, spinal or epidural anaesthesia and prior to intravascular administration of iodinated contrast agents. It should not be restarted until at least 48 hours after the procedure. Caution when used in combination with insulin or other oral antidiabetics (hypoglycaemia risk).

INTERACTIONS
Increased risk of lactic acidosis with alcohol intoxication. Some products can adversely affect renal function, which may increase the risk of lactic acidosis, e.g. NSAIDs and selective cyclooxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. More frequent blood glucose monitoring may be required with products with hyperglycaemic activity e.g. glucocorticoids and sympathomimetics. OCT inhibitors/inducers may alter the efficacy of metformin.

PREGNANCY AND LACTATION
Should not be used patient plans to become pregnant and during pregnancy – insulin should be used in this case to control diabetes. Breast-feeding not recommended with metformin.

SIDE EFFECTS
Taste disturbance, nausea, vomiting, diarrhoea, abdominal pain, loss of appetite. ***Very rare***: Lactic acidosis, decrease of vitamin B12 absorption, liver function test abnormalities, hepatitis, erythema, pruritus, urticaria.

PACKAGE QUANTITY AND COST
28 x 500mg £1.20: 56 x 500mg £2.39: 28 x 750mg £1.44: 56 x 750mg £2.88: 28 x 1000mg £1.92: 56 x 1000mg £3.83

LEGAL CATEGORY
POM

MARKETING AUTHORISATION NUMBERS
PL29831/0655 - 0657

MARKETING AUTHORISATION HOLDER
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK, from whom further information is available.

DATE
June 2018

Adverse reactions should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Wockhardt UK Ltd (01978 661261).