Prescribing Information:  TOCTINO (alitretinoin) 10mg or 30mg capsules Before prescribing, please refer to the Summary of Product Characteristics (SPC).

Presentation: Soft capsules containing 10mg or 30mg of alitretinoin. Indication: Adults, 18 years or older, with severe chronic hand eczema unresponsive to potent topical corticosteroids. Dosage and administration: To only be prescribed by Dermatologists, or physicians experienced in using systemic retinoids and understand risks of retinoid therapy and monitoring requirements. Prescriptions in women of childbearing potential should be limited to 30 days and continuation requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur same day; dispensing Toctino should occur within a maximum of 7 days of the prescription. Recommended starting dose is 30mg once daily by mouth with main meal preferably at same time each day for 12 to 24 weeks depending on response. Consider dose reduction to 10mg in patients with unacceptable adverse reactions to 30mg. Discontinue treatment in patients who have achieved clear or almost clear hands earlier than 24 weeks or in patients who still have severe disease after 12 weeks of continuous treatment. In the event of relapse, patients may benefit from further treatment courses of Toctino. Contraindications: Pregnancy, women of child bearing potential unless all conditions of the Pregnancy Prevention Programme (PPP) are met, breast-feeding, hepatic impairment, severe or end-stage renal impairment, uncontrolled hypercholesterolaemia or hypertriglyceridaemia, uncontrolled hypothyroidism, hypervitaminosis A, hypersensitivity to alitretinoin, other retinoids or excipients, allergy to peanut or soya, rare hereditary fructose intolerance and concomitant treatment with tetracyclines. Precautions and warnings: Toctino is teratogenic. All conditions of the PPP must be met in women of child bearing potential. As a minimum female patients at risk of pregnancy must use at least one effective method of contraception, preferably two complementary forms including a barrier method, during and at least 1 month before and 1 month after stopping treatment. Full patient information about teratogenic risk and the strict pregnancy prevention measures as specified in the PPP should be given by the physician to all patients, both male and female. Please refer to the SPC for further details. Patients must not share medication or donate blood during therapy and for 1 month after. Prior to starting and at each visit during therapy, patients should be asked about any psychiatric disorder, depression, or mood disturbance. Stop Toctino if patients develop depression, mood disturbance, psychosis or aggression. Effects of UV light may be enhanced therefore patients should avoid excessive exposure to sunlight and sun lamps, and where necessary use high sun protection. Dry eyes and decreased night vision has been associated with treatment; symptoms usually resolve after discontinuation. Patients experiencing visual difficulties should be referred to an ophthalmologist. Withdrawal of alitretinoin may be necessary. Discontinue treatment immediately if patient develops signs of benign intracranial hypertension. Monitor serum triglycerides and cholesterol and discontinue treatment if uncontrolled hypertriglyceridaemia or symptoms of pancreatitis occur. Reduce dose or discontinue treatment if persistently raised liver transaminases. More frequent monitoring of serum lipids and/or blood glucose may be required in patients with diabetes, obesity, cardiovascular risk factors or a lipid metabolism disorder. Not recommended in patients with moderate renal impairment. Consider inflammatory bowel disease if severe diarrhoea and stop Toctino immediately. Stop treatment if severe allergic reaction occurs. Interactions: Consider dose reduction to 10mg if co-administered with; CYP3A4 inhibitors; potent CYP2C9 inhibitors or potent CYP2C8 inhibitors. Co-administration with amiodarone is not recommended and caution advised when co-administering with other medicines that are substrates for CYP2C8 substrates. Do not take concurrently with Vitamin A or other retinoids as may cause hypervitaminosis A. Concurrent use may reduce simvastatin plasma levels. Avoid concurrent use with tetracyclines as may increase the risk of benign intracranial hypertension. Fertility, pregnancy and lactation: Absolute contraindication in pregnancy. If pregnancy occurs in spite of the pregnancy prevention precautions during treatment or in the month after, there is a high risk of very severe serious malformation of the foetus. Stop treatment and refer to a physician specialised in teratology. Detected in semen but drug accumulation not expected and negligible effect on plasma levels of the female partner or a foetus. Effects on ability to drive and use machines: Potential decreased night vision and caution should be given to patients when driving or operating machines. Undesirable effects: Very common (≥1/10) Headaches, lipid disorders. Common (≥1/100 <1/10) Depression, dizziness, anaemia, increased iron binding capacity, decreased monocytes, increased thrombocytes, thyroid function disorders, conjunctivitis, dry eyes, eye irritation, tinnitus, flushing, hypertension, nausea, dry mouth, vomiting, increased transaminases and creatinine phosphokinase, dry skin and lips, cheilitis, eczema, dermatitis, erythema, alopecia, arthralgia, myalgia, fatigue. Rare (≥ 1/10000 <1/1000) Benign intracranial hypertension. Unknown Anaphylaxis, hypersensitivity, suicidal ideation, inflammatory bowel disease. Consult SPC in relation to other adverse events. Storage instructions: Store in the original packaging and protect from light. Marketing Authorisation (MA) holder: GlaxoSmithKline UK Limited, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. NHS Price & MA Numbers: 10mg (PL 19494/0252) and 30mg (PL 19494/0253), 30 capsules = £411.43. Legal category: POM. Date of preparation: June 2016. Zinc code: UK/ART/0010/13(5) Toctino® is a registered trade mark of Stiefel Laboratories, Inc.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Stiefel, a GSK company on 0800 221 441.