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. 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. Recommended starting dose is 30mg once daily by mouth with main meal at same time each day for 12 to 24 weeks depending on response. Consider dose reduction to 10mg in patients with unacceptable adverse reactions. Discontinue treatment in patients who have achieved clear or almost clear hands earlier than 24 weeks or if there is still 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. At least one month after the patient has started using contraception, and shortly (preferably a few days) prior to the first prescription, do a medically supervised pregnancy test, to ensure the patient is not pregnant. Evaluate individual circumstance, when choosing contraception, involving the patient in the discussion. At least one highly effective method (i.e. a user-independent form) or two complementary user-dependent forms of contraception should be used during and at least 1 month before and 1 month after stopping treatment. Stop treatment if pregnancy occurs and refer patient to a physician specialised or experienced in teratology. If pregnancy occurs after stopping treatment there remains a risk of severe and serious malformation of the foetus, which persists until within one month of stopping treatment.

Full patient information about teratogenic risk and the strict pregnancy prevention measures as specified in the PPP must be given 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. Take particular care in patients with a history of depression. Prior to initiation of Toctino and at each visit during therapy, ask patients about any psychiatric disorder, depression, or mood disturbance and stop treatment if any of these develop. Effects of UV light may be enhanced therefore 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. Refer patients experiencing visual difficulties 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 pancreatitis occur. Reduce dose or discontinue 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. Do not co-administer with amiodarone and caution when co-administering with other medicines that are substrates for CYP2C8. Do not take 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.** Alitretinoin is a potent teratogen and is highly lipophilic, therefore the passage into human milk is very likely, so is contra-indicated in breast feeding. **Effects on ability to drive and use machines:** Potential decreased night vision. Caution patients about driving or operating machines. **Undesirable effects: Very common (≥1/10)** Headaches, lipid disorders. **Common (≥1/100 <1/10)**, 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. **Uncommon (≥ 1/1000 <1/100)** Blurred vision, cataract, epistaxis, dyspepsia, pruritus, rash, skin exfoliation, asteatotic eczema, exotosis, ankylosing spondylitis. **Rare (≥ 1/10,000 <1/1000)** Depression, depression aggravated aggressive tendencies, anxiety, mood alterations, Benign intracranial hypertension. **Very Rare (<1/10,000)** Suicide, suicide attempt. Suicidal ideation, psychotic disorder, abnormal behaviour. **Unknown** Anaphylaxis, hypersensitivity, inflammatory bowel disease. Consult SPC in relation to other adverse events. **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**: July 2018. **Zinc code:** UK/ART/0010/13(6). 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.