



Clearance with Toctino®

Toctino treats hand eczema from the inside –
so patients can do more on the outside^{1,2}

Target the underlying cause, not just the symptoms –
raise your expectations of treatment with Toctino

Toctino®  (alitretinoin)
Restore from within

Toctino is indicated for the use in adults who have severe chronic hand eczema unresponsive to treatment with potent topical corticosteroids.²

References: 1. Ruzicka T, Lynde CW, Jemec GBE, et al. Efficacy and safety of oral alitretinoin (9-cis retinoic acid) in patients with severe chronic hand eczema refractory to topical corticosteroids: results of a randomized, placebo-controlled, multicentre trial. *Br J Dermatol*. 2008;158: 808–817 2. Toctino Summary of Product Characteristics. Basilea Pharmaceutica; 2011

Toctino® (alitretinoin) 10 mg or 30 mg Capsules Prescribing Information: **Name of Medicine:** Toctino® [alitretinoin] 10 mg or 30 mg Capsules **Non proprietary name:** Alitretinoin **Presentation:** Soft capsules containing 10 mg or 30 mg of alitretinoin. **Indication:** Severe chronic hand eczema in adults that is unresponsive to treatment with potent topical corticosteroids. Predominantly hyperkeratotic features are more likely to respond to treatment than pompholyx. **Dosage and administration:** Toctino should only be prescribed by dermatologists or physicians with experience in the use of systemic retinoid therapy. The recommended dose range is 10–30 mg once daily, to be taken orally with a meal. The recommended starting dose is 30 mg once daily. A dose reduction to 10 mg once daily may be considered in patients with unacceptable adverse reactions to the higher dose. "High risk" patients with diabetes, obesity, cardiovascular risk factors or lipid metabolism disorders should be initiated on 10 mg once daily and titrated up to 30 mg once daily if necessary. A treatment course can be given for 12 to 24 weeks depending on response. In the event of relapse, patients may benefit from further treatment courses. Prescriptions for women of childbearing potential should be limited to 30 days and dispensed within 7 days of the prescription in accordance with the Pregnancy Prevention Programme. **Contra-indications:** Pregnancy is an absolute contraindication to treatment with Toctino. Use during pregnancy or in women of childbearing potential is contraindicated unless all conditions of Pregnancy Prevention Programme are met. If pregnancy does occur in spite of the pregnancy prevention precautions during treatment with Toctino or in the month following discontinuation of therapy, there is a high risk of very severe and serious malformation of the foetus. Please refer to the Toctino Summary of Product Characteristics for further details. **If pregnancy occurs, Toctino should be stopped immediately and the patient referred to a physician specialising or experienced in teratology for advice.** Toctino is contraindicated during breastfeeding. Toctino is contraindicated in patients with hepatic insufficiency, severe renal insufficiency, uncontrolled hypercholesterolaemia, hypertriglyceridaemia, hypothyroidism, hypervitaminosis A, hypersensitivity to alitretinoin, other retinoids or excipients, allergy to peanut or soya, hereditary fructose intolerance and concomitant tetracycline treatment. **Precautions and warnings:** Not recommended in patients under 18 years of age. Male fertility may be compromised. Patients should be reminded not to share medication or donate blood during therapy or for 1 month following therapy with Toctino. Psychiatric disorders have been seen with retinoids, including Toctino, therefore particular care should be taken in patients with a history of depression. Patients should be observed for signs of depression and referred for appropriate treatment if necessary. Effects of UV light may be enhanced and patients should avoid excessive exposure to sunlight, unsupervised use of sun lamps and should use appropriate sun protection of at least SPF 15. Patients experiencing visual difficulties should be referred to an ophthalmologist and treatment discontinuation may be required. Decreased night vision has been reported and patients should be warned to be cautious when driving or operating machinery. Patients who develop signs and symptoms of benign intracranial hypertension including headache, nausea and vomiting, visual disturbances and papilloedema should discontinue treatment immediately. Serum cholesterol and triglycerides should be monitored. Treatment should be discontinued if hypertriglyceridaemia cannot be controlled at an acceptable level or if symptoms of pancreatitis occur. In "high risk" patients with diabetes, obesity, cardiovascular risk factors or lipid metabolism disorders, more frequent serum lipid checks may be necessary. Dose reduction or discontinuation should be considered in the event of persistent clinically relevant elevation of liver transaminases. If severe diarrhoea is observed, diagnosis of inflammatory bowel disease should be considered and treatment discontinued immediately. Severe allergic reactions necessitate interruption of therapy and careful monitoring. Please refer to the Toctino Summary of Product Characteristics for further details. **Interactions:** Concomitant use of St John's Wort may cause failure of combined hormonal contraceptives. Concomitant use of vitamin A or other retinoids may cause hypervitaminosis A. Concomitant use of tetracyclines may increase the risk of benign intracranial hypertension. **Common adverse effects:** Very common (≥10%); headache, hypertriglyceridaemia, hypercholesterolaemia, decreased LDL. **Common (≥1%; <10%):** anaemia, increased iron binding capacity, decreased monocytes, increased thrombocytes, decreased TSH, decreased free T4, conjunctivitis, dry eyes, eye irritation, flushing, increased liver transaminases, dry skin and lips, cheilitis, eczema, dermatitis, erythema, alopecia, arthralgia, myalgia, increased blood creatinine phosphokinase. **Serious adverse effects:** Uncommon (≥0.1%; <1%): blurred vision, cataract, epistaxis, ankylosing spondylitis. **Rare (≥0.01; <0.1%):** benign intracranial hypertension, vasculitis. **Overdose:** reversible adverse effects consistent with retinoid toxicity, including severe headache, diarrhoea, facial flushing and hypertriglyceridaemia. Please refer to the Toctino Summary of Product Characteristics for full details of adverse effects with Toctino. **Storage instructions:** Store in original packaging and protect from light. **Marketing authorisation number and NHS List Price:** PL32205/0001/0001 Toctino 10 mg 30 capsule pack £411.43; PL32205/0001/0002 Toctino 30 mg 30 capsule pack £411.43. **Legal category:** POM. **Name and address of authorisation holder:** Basilea Medical Ltd, 14/16 Frederick Sanger Road, The Surrey Research Park, Guildford, Surrey, GU2 7YD. Toctino® is a registered trademark of Basilea Pharmaceutica International AG. **Date of preparation of prescribing information:** October 2011. AU110053

