

Assessment of chronic hand eczema patients for Toctino▼ (alitretinoin) treatment using the Physicians Global Assessment (PGA) scale and DLQI score

Background: NICE recommendations for Toctino include the use of the PGA severity scale and the DLQI instrument (see reverse of this pad for a summary of NICE guidance)

Instructions for use:

- The table below should be used by healthcare professionals to assess clinical severity according to the PGA scale
- The separate DLQI questionnaire should be used by patients to assess impact on quality of Life (full instructions for use can be found at: <http://www.dermatology.org.uk/quality/quality-dlqi-info.html>)
- You may wish to document and date the results of both assessments on this sheet and keep with the patients notes to facilitate audit
- A carbon copy is also provided, should this be required by third parties (eg pharmacy, PCT)

PGA Severity	Features	Intensity	Area Involved
Severe (NICE eligibility criterion)	Erythema, Scaling, Hyperkeratosis/Lichenification	At least one moderate or severe	>30% of affected hand surface
	Vesiculation, Oedema, Fissures, Pruritus/Pain	At least one severe	
Moderate	Erythema, Scaling, Hyperkeratosis/Lichenification	At least one mild or moderate	10%-30% of affected hand surface
	Vesiculation, Oedema, Fissures, Pruritus/Pain	At least one moderate	
Mild	Erythema, Scaling, Hyperkeratosis/Lichenification	At least one mild	Less than 10% of affected hand surface
	Vesiculation, Oedema, Fissures, Pruritus/Pain	At least one mild	
Almost clear (NICE stopping criterion)	Erythema, Scaling, Hyperkeratosis/Lichenification	At least one mild	Less than 10% of affected hand surface
	Vesiculation, Oedema, Fissures, Pruritus/Pain	Absent	
Clear (NICE stopping criterion)	Erythema, Scaling, Hyperkeratosis/Lichenification	Absent	Not detectable
	Vesiculation, Oedema, Fissures, Pruritus/Pain	Absent	

Date of assessment:

PGA category:

DLQI score (from separate sheet provided to patient):

Treatment decision:

Physician signature:

DERMATOLOGY LIFE QUALITY INDEX

Hospital No:
Name:
Address:

Date:
Diagnosis:

DLQI
Score:

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick one box for each question.

- | | | | | |
|-----|---|-------------------------------------|-------------------------------------|---------------------------------------|
| 1. | Over the last week, how itchy, sore, painful or stinging has your skin been? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | |
| 2. | Over the last week, how embarrassed or self conscious have you been because of your skin? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | |
| 3. | Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden ? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 4. | Over the last week, how much has your skin influenced the clothes you wear? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 5. | Over the last week, how much has your skin affected any social or leisure activities? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 6. | Over the last week, how much has your skin made it difficult for you to do any sport ? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 7. | Over the last week, has your skin prevented you from working or studying ? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| | If "No", over the last week how much has your skin been a problem at work or studying ? | A lot <input type="checkbox"/> | A little <input type="checkbox"/> | |
| | | Not at all <input type="checkbox"/> | | |
| 8. | Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives ? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 9. | Over the last week, how much has your skin caused any sexual difficulties ? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 10. | Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time? | Very much <input type="checkbox"/> | A lot <input type="checkbox"/> | |
| | | A little <input type="checkbox"/> | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |

Please check you have answered EVERY question. Thank you.

Summary of NICE guidance for the use of Toctino

- Alitretinoin is recommended, within its licensed indication, as a treatment option for adults with severe chronic hand eczema that has not responded to potent topical corticosteroids if the person has:
 - Severe disease defined by the Physicians Global Assessment (PGA) and
 - A Dermatology Life Quality Index (DLQI) score of 15 or more
- Alitretinoin treatment should be stopped:
 - As soon as an adequate response (hands clear/almost clear) has been achieved or
 - If the eczema remains severe (as defined by the PGA) at 12 weeks or
 - If an adequate response (hands clear/almost clear) has not been achieved by 24 weeks
- Only dermatologists or physicians with specialist experience in managing both severe hand eczema and the use of systemic retinoids should start and monitor treatment with alitretinoin

When using DLQI, healthcare professionals should take into account any physical, sensory or learning disabilities, or other communication difficulties that could affect the responses to the DLQI. In such cases, healthcare professionals should ensure that the DLQI continues to be a sufficiently accurate measure

Toctino® (alitretinoin) 10mg or 30mg Capsules Prescribing Information Name of Medicine: Toctino® (alitretinoin) 10mg or 30mg Capsules **Non proprietary name:** Alitretinoin **Presentation:** Soft capsules containing 10mg or 30mg 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 10-30mg once daily, to be taken orally with a meal. The recommended starting dose is 30mg once daily. A dose reduction to 10mg 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 10mg once daily and titrated up to 30mg 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 other retinoids, 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 10mg 30 capsule pack £411.43; PL32205/0001/0002 Toctino 30mg 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 Pharmaceuticals International AG **Date of preparation of prescribing information:** August 2008. ALI080051

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Basilea Pharmaceuticals on 01483 790023.