ALITRETINOIN

What are the aims of this leaflet?

This leaflet has been written to help you understand more about alitretinoin. It tells you what it is, how it works, how it is used and where you can find out more about it.

What is alitretinoin and how does it work?

Alitretinoin (trade name Toctino) is a drug belonging to a group of medications called retinoids. Alitretinoin is a form of vitamin A and works by reducing skin cell turnover. It also helps to reduce skin inflammation.

What skin conditions are treated with alitretinoin?

Alitretinoin is used for severe persistent hand eczema which has not responded to other treatments including very strong topical steroid ointments.

Will alitretinoin cure my skin condition?

Alitretinoin is not a cure but most people will see a gradual improvement in their skin within a few weeks of starting the treatment. This improvement should then continue whilst taking the medication and can continue after it has been stopped. A course can be given for up to 6 months and can be repeated if the hand eczema recurs.

What dose should I take?

The usual dose is 30 mg once daily. This can be reduced to 10 mg daily if side-effects do not settle down after a few weeks. Patients with diabetes, high fat levels in the blood or heart disease can start on 10 mg and increase to 30 mg within a few weeks if they are tolerating the medication.
Alitretinoin is absorbed into the body with fats. It is best to take the medication after a meal.

**When should I not take alitretinoin?**

Female patients must not take alitretinoin in pregnancy. If a woman becomes pregnant whilst taking alitretinoin it is possible that the baby will be harmed, and a termination of pregnancy will be recommended.

Please see below for more information on the Pregnancy Prevention Programme.

Women who have taken alitretinoin should wait for at least 5 weeks after stopping treatment before trying to conceive.

Female patients should stop the medication immediately if pregnancy occurs on treatment and contact their GP and dermatologist. This medication should not be taken during breast feeding.

**Peanut or soya allergy**

Alitretinoin contains soya oil. Occasionally, patients with soya allergy might react to the trace levels of soya proteins in soya oil. Exceptionally rarely, patients with peanut allergy might have a cross reaction to soya proteins in soya oil. You should inform your doctor and pharmacist if you think you may have an allergy to soya.

**What are the possible side-effects of alitretinoin?**

Most people taking alitretinoin experience dryness of the skin, particularly of the lips, inside the nose and eyes. Nosebleeds may occur if the skin inside the nose becomes very dry.

Using a moisturiser and lip salve regularly will help manage these symptoms. Dry eyes may make the wearing of contact lenses a little uncomfortable; this may be helped by using artificial tears.

As a result of the skin becoming dry and cracked, the risk of skin infection is increased. Wounds may also take longer to heal and the skin may feel fragile and peel with friction.
Whilst taking alitretinoin, and for six months afterwards, your skin will be more delicate than usual; hair removal using waxing and epilation, dermabrasion and laser treatment should be avoided. Shaving is normally tolerated, but use of a moisturiser afterwards is advisable.

Alitretinoin may affect your ability to see at night. On rare occasions these vision changes may be permanent.

This requires caution in people whose job requires good night vision, such as drivers and those who operate heavy machinery. You should discuss with your employer before taking this treatment, and avoid driving and/or operating heavy machinery if you experience these symptoms.

Airline pilots will not be able to continue their job while on alitretinoin and are advised to discuss this with their employer before starting the medication, and check with current Civil Aviation guidelines.

Headache is a common side effect of alitretinoin, affecting up to one person in 5 who takes it. It usually goes away of its own accord, or with paracetamol and increasing fluid intake. Reducing the dose of Alitretinoin may occasionally be necessary.

A very rare (1 in 10,000) side effect is raised pressure in the brain, this causes severe headache, nausea, vomiting and blurred vision.

Alitretinoin may sometimes cause an increase in the levels of fats in your blood, a decrease in your thyroid function or abnormalities in blood tests for liver function. A blood test is usually requested during treatment to monitor any potential side-effects.

Other common side-effects include flushing and muscle aches.

A number of more serious side effects may occur although these are fortunately rare. Alitretinoin can lead to changes in mood and/or behaviour and less commonly, unusual experiences including thoughts of self-harm and suicide. There have also been reports of patients attempting suicide. If you have ever had low mood, suicidal ideas or any other mental health problem, please discuss this with your doctor before starting treatment. If you have a history of depression your dermatologist may ask a psychiatrist to see you before starting alitretinoin to determine if it is safe for you to take this treatment. **If you or your friends/relatives feel that your mood or behaviour is changing, or if you start having thoughts of self-harm**
whilst taking alitretinoin, please inform your doctor and stop taking it immediately. Your doctor will then discuss it with you and advise if it is safe to take in the future.

**Other important considerations**

Neither men nor women can donate blood when taking alitretinoin or for at least one month after stopping the medication.

Medication should not be shared with others even if they have severe hand eczema.

Alitretinoin may increase your skin’s sensitivity to the sun. You should therefore avoid direct sun exposure whilst taking this medication. Where necessary a sun-protection product with a high protection factor of at least SPF 30 should be used. You should also avoid the use of sun beds.

**Can I drink alcohol whilst taking alitretinoin?**

Yes but not to excess. You should not exceed the government recommended guidelines for weekly alcohol consumption (no more than 14 units for females or 21 units for males).

**Can I take other medications at the same time as alitretinoin?**

Some medications may interact with alitretinoin. It is important to discuss what you are taking with your doctor and pharmacist before taking any new prescribed or over the counter medications and supplements.

Medications to avoid while taking alitretinoin include:

- Tetracycline antibiotics
- Methotrexate
- Vitamin A supplements

This is not a complete list and it is important that you always inform your doctor and pharmacist that you are taking alitretinoin, and read the in-pack leaflet.

**What is the Pregnancy Prevention Programme?**
All women considered to be able to conceive should be entered into the Pregnancy Prevention Programme whilst taking their course of alitretinoin, in order to minimise the risk of pregnancy.

- Before starting alitretinoin you must use at least one, and preferably two, forms of adequate contraception for at least one month before starting treatment. It is necessary to discuss general aspects of contraception with your doctor or nurse.
- Usually one form of contraception will be a barrier method such as condoms or a cap.
- Combined contraceptive pills are considered to be effective. Certain antibiotics (e.g. amoxicillin) and herbal products (e.g. St John’s Wort) can interfere with hormonal contraceptives (‘The Pill’) making them less effective.
- You will be given your first prescription for alitretinoin after having a negative pregnancy test at the clinic.
- Ideally you should start treatment on day 2 or 3 of your menstrual cycle.
- Each month you will attend the clinic for a pregnancy test and you will have a final pregnancy test 5 weeks after finishing treatment.
- You will only be supplied with 30 days of treatment on each visit following a negative pregnancy test.
- You must collect your prescription for alitretinoin from the pharmacy within 7 days of it being signed by your doctor.
- Contraception needs to be continued after treatment is stopped, for a further month.
- Once you have completed your course of alitretinoin and been advised to stop alitretinoin by your doctor, you should not take any further capsules. Any capsules left over should be returned to the hospital or your pharmacist.

**Do all women have to enter the Pregnancy Prevention Programme?**

Women who are unable to become pregnant due to medical reasons, or who have been sterilised, may be excluded from the Pregnancy Prevention Programme. In exceptional circumstances, females capable of becoming pregnant but who are not sexually active may be exempted from the Pregnancy Prevention Programme.

**Where can I find out more about alitretinoin?**
If you would like any further information about alitretinoin, or if you have any concerns about your treatment, you should discuss them with your doctor or pharmacist. This information leaflet does not include all the side-effects this drug can cause. For full details, please see the drug information leaflet that comes with your medicine. Your doctor will assess your medical circumstances and draw your attention to side-effects that may be relevant to you.

Links to other sites:

http://www.dermnetnz.org/treatments/alitretinoin.html

http://www.medicines.org.uk/emc/medicine/21166

http://www.eczema.org

For details of source materials used please contact the Clinical Standards Unit (clinicalstandards@bad.org.uk).

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists’ Patient Information Lay Review Panel

BRITISH ASSOCIATION OF DERMATOLOGISTS
PATIENT INFORMATION LEAFLET
PRODUCED NOVEMBER 2015
REVIEW DATE NOVEMBER 2018