



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 (brand name Toctino) belongs to a group of drugs called retinoids, which are closely related to vitamin A. It works by reducing skin cell turnover and also helps to reduce skin inflammation.

What skin conditions are treated with alitretinoin?

Alitretinoin is licensed for severe persistent hand eczema which has not responded to other treatments including very strong steroid creams or 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.

As alitretinoin is better absorbed into the body with food containing some fat, it is best to take the medication after a meal.

Caution for patients of child-bearing potential

Patients must not take alitretinoin in pregnancy. If a person becomes pregnant whilst taking alitretinoin or 4 weeks after they finish the course, there is a high risk that the baby will be harmed with severe and serious defects (such as abnormal appearance or intellectual disability) and an increased risk of miscarriage.

If you do become pregnant, or suspect that you may be pregnant, you must stop the medication immediately and contact your doctor, so you may be referred to a specialist pregnancy clinic. A termination of pregnancy will be recommended. You should not breast feed while taking alitretinoin and for a month after completing treatment.

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

What is the Pregnancy Prevention Programme?

All women with child-bearing potential should be entered into the Pregnancy Prevention Programme whilst taking their course of alitretinoin, in order to minimise the risk of pregnancy. There are rules that the government body, the MHRA, has produced which doctors and pharmacists must follow:

- Before starting alitretinoin you must use at least one, and preferably two, forms of effective contraception for at least one month before starting treatment. It is necessary to discuss general aspects of contraception with your doctor or nurse.
- 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.
- However, oral progestogen-only contraceptives ("the mini pill") are NOT considered effective.
- Barrier methods, such as condoms and caps, should not be used alone, but can be used in conjunction with other contraceptive methods.
- 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.

Do all women have to enter the Pregnancy Prevention Programme?

Women who are unable to become pregnant due to medical reasons, or have been sterilised, or had a hysterectomy, or had both ovaries surgically removed, or postmenopausal (defined as more than a year since last menstrual period) 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.

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. Extremely rarely, patients with peanut allergy might also have a reaction to the soya proteins in soya oil. You should inform your doctor and pharmacist if you think you may have an allergy to soya or peanut.

What are the common side effects of alitretinoin?

In general, dryness of the skin, lips, and eyes is the most common side effect. Using a moisturiser and lip balm regularly will help. In more severe cases, this can turn into eczema and may require additional treatment. Nosebleeds may occur if the skin inside the nose becomes very dry. Dry eyes may make the wearing of contact lenses a little uncomfortable and may be helped by using artificial tears eye drops available over the counter.

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, epilation, dermabrasion, or laser treatment, as well as tattoos and piercings

should be avoided. Shaving is normally tolerated, but use of a moisturiser afterwards is advisable.

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.

Alitretinoin can rarely affect your vision, in particular the ability to see at night. If you develop difficulties seeing at night or in dark situations you should avoid driving and/or operating heavy machinery. Patients whose jobs may be impacted by this, such as drivers, airline pilots, people in the military, and those who operate heavy machinery, are advised to discuss this with their employer before starting the medication, and check with current Civil Aviation guidelines. These night vision changes may be permanent in extremely rare circumstances.

Headache is a common side effect of alitretinoin, affecting up to one in 5 people who take 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.

Alitretinoin may sometimes cause an increase in the levels of fats in your blood (which can lead to inflammation of the pancreas), a decrease in your thyroid function, or inflammation of the liver. Blood tests will be requested during treatment to monitor any potential side effects. Other common side-effects include flushing and muscle aches.

What are the rare side effects of alitretinoin?

A number of more serious side effects may occur although these are fortunately rare. Alitretinoin can lead to changes in mood and/or behaviour (between 1 in 1,000 and 1 in 10,000 chance) and less commonly, unusual experiences including thoughts of self-harm and suicide (less than 1 in 10,000 chance). 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 dermatologist 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 dermatologist will then discuss it with you and advise if it is safe to take in the future.**

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

Sexual side effects, such as male impotence may occur following treatment with alitretinoin, but this has only ever been shown in animal studies and not proven in humans.

There have been few rare reports of patients developing inflammatory bowel disease, such as Crohn's disease or ulcerative colitis, whilst on alitretinoin. If you develop severe or bloody diarrhoea whilst on alitretinoin, please stop taking your medication immediately and see your GP on the same day or attend the nearest Accident and Emergency department depending on the severity of your symptoms and how you feel.

This is not a complete list of side effects, and if you do develop any new problems while taking alitretinoin please inform your doctor or nurse.

Are there any other precautions whilst taking alitretinoin?

You cannot donate blood when taking alitretinoin and for at least one month after stopping the medication in case the blood is given to a pregnant woman.

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

There has been no known adverse effect on the pregnancy if a man taking alitretinoin fathers a child even though small amounts of alitretinoin is found in semen.

Alitretinoin has a similar name to other medications and patients should always double check the packaging to ensure that they have not been given the wrong medication.

Can I drink alcohol whilst taking alitretinoin?

Yes, but not to excess as alcohol can also cause inflammation of the liver. You should not exceed the government recommended guidelines for alcohol consumption (no more than 14 units per week).

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 (including multi-vitamins containing vitamin A)

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.

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>

<https://www.nice.org.uk/guidance/TA177>

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

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