

FACT SHEET: ISOTRETINOIN INFORMATION FOR PATIENTS

You have been prescribed isotretinoin (=Roaccutane, Oratane) for your acne. It is used for acne which does not respond to other treatments, scarring and cystic acne and is a tablet similar to vitamin A.

You will be treated for a number of months with this tablet (6-12 months), depending on your body weight, the extent of involvement and clinical progress.

It is the total dose over a prolonged period of time which will result in the improvement of your acne. It is therefore important that you take the tablet at the prescribed dose and do not take more than has been recommended.

You must not give these tablets to anyone else as it may cause major side effects including birth deformities in an unborn baby.

70-80% of patients will get a cure from their acne at the end of the course of treatment. You will continue to improve even after the course is finished but in some people their acne will return and another course may be required.

SIDE EFFECTS

There are a number of side effects associated with the use of isotretinoin and most people will get some side effects to some degree. They may be reduced or eliminated by reducing the dose of tablet you take. Many of the more serious effects are extremely rare. **The vast majority of patients have no long-term problems and tolerate the treatment quite well.** Very rarely the skin and eyes can be persistently dry

Isotretinoin **causes birth deformities** if you are pregnant or fall pregnant while on treatment. It is important that you don't fall pregnant while on the drug or for at least 2 months after finishing treatment.

For female patients it is common to be requested to have a pregnancy test before treatment commences. If you think you are pregnant stop the isotretinoin and contact your Doctor immediately. Both men and women must not donate blood to the blood bank while on isotretinoin as the blood could affect a pregnant woman's baby if she receives it.

Other side effects of isotretinoin include:

- *Dryness of the skin* especially the lips, eyes and facial skin. Almost everyone gets this side effect.
- *Nose bleeds*
- Eye dryness and irritation are also common. This may be a problem if you wear contact lenses and you may have to wear glasses instead. If you have

persistent eye problems even after using eye drops let your Doctor know this. Isotretinoin can also effect your night vision, it is therefore not advisable to drive at night while taking this treatment, especially if you notice that your night vision has been impaired.

- Some people develop some hair loss which usually recovers.
- Occasionally people's hands and feet peel.
- Isotretinoin can also cause you to be easily sunburnt, you will need to wear a sunscreen if you are outside especially in summer.
- Some skin bacteria can flourish while on Isotretinoin.
- Ingrown and irritated nails can occasionally occur. Let your Doctor know if you have nail problems.
- Yellowish crusted scabs may be a sign of skin infection and a topical or oral antibiotic may be needed to clear up the problem. A topical antibiotic may need to be put inside your nose to help remove the bacteria.

All of these effects are improved by reducing the dose and return to normal after treatment is finished. It is extremely rare for any side effect problems to persist on stopping treatment in regards to these side effects. Because acne creams cause skin irritation you should stop topical creams for acne which you may have been using prior to treatment with Isotretinoin.

Some people notice that their acne gets worse in the first few weeks after starting treatment.

If there is a **marked deterioration in your acne** stop the isotretinoin and speak to your Doctor immediately. Rarely the tablet can cause a severe flare of your acne and result in scarring. Some people need very low doses initially so this doesn't happen. Some people with very angry and inflamed acne need to be on prednisone (a steroid tablet) and/or antibiotics (erythromycin) when this happens.

Muscle aches and pains and **joint aches** are common especially early in treatment. They tend to improve with time and improve with dose reduction. If you play strenuous sport or weight lifting this may be a problem and you will need to discuss this with your doctor. Gentle exercise is not a problem. Panadol or anti-inflammatory tablets may be used to help settle these such as ibuprofen from a chemist.

Headaches sometimes occur and if they are mild and transient this is not a problem. If you have persistent or severe headaches stop the tablets. Rarely the pressure inside your head can rise causing headaches which persist and are severe. There is often an association of visual changes and nausea and vomiting with headaches if this rare complication occurs. This is reversible with stopping treatment. There is an increased risk of this if you also take tetracycline antibiotics at the same time. These antibiotics are the common ones used for acne. Therefore you must not take tetracycline antibiotics while on Isotretinoin.

Depression and lethargy can occur especially if you have had depression before. Let your doctor or family know if you feel more depressed, unhappy or moody as the

tablet may need to be stopped if depression is a problem. Studies have shown that the level of depression and suicide is higher or similar in people with bad acne without treatment with Isotretinoin.

Isotretinoin can also have an effect on the **blood fat levels**. This is the most common blood abnormality associated with isotretinoin. This is often worse if you already have high blood fats.

Blood fat levels will need to be monitored during treatment. Being overweight, having diabetes, a high fat diet and alcohol can worsen the blood fat problems

Isotretinoin can also have **effects on the liver**. This may not be noticed by you so blood tests will be performed regularly to monitor this. Some mild blood changes are OK but if significant Isotretinoin may need to be stopped. This is very uncommon. Persistent problems with the liver are extremely rare with Isotretinoin. Having a liver problem before treatment, being obese, having diabetes and high alcohol intake increases the risk of liver side effects. Alcohol should be kept to a minimum while on Isotretinoin.

Uncommonly the white blood cells can drop and treatment may need to be ceased.

Because of these side effects you will need to be monitored every 6-8 weeks, more frequently if problems arise. You will need to have some blood tests before starting isotretinoin and then 6 -8 weeks into treatment.

Other problems very rarely occur:

- Thick scars can develop where the acne has been. This can occur in untreated acne as well.
- Skin rashes
- Skin fragility.
- Rapidly growing skin lesions that bleed easily

SERIOUS COMPLICATIONS:

Rhabdomyolysis- is a serious syndrome due to a direct or indirect muscle injury. It results from the death of muscle fibers and release of their contents into the bloodstream. This can lead to serious complications such as renal (kidney) failure. If the muscle aches are very severe, do stop the treatment.

Inflammatory bowel disease which involves chronic inflammation of all or part of your digestive tract characterised by bloody diarrhoea, abdominal pain & cramping, lethargic, fever etc. If you experience such symptoms, treatment must be stop.

While on isotretinoin please avoid the following:

- Alcohol
- Vitamin A in vitamin supplements
- Topical acne treatments you may have used before as these will have an additive irritant effect Stop antibiotics for acne such as minomycin.
- Do not wax to remove hairs as your skin may tear away. Do not have facials. Do not have electrolysis to remove hairs. Hair colouring or perming should be avoided as your hair is more fragile while on isotretinoin.
- Do not have yours ears or other parts of your skin pierced as bad scarring may result.

LOOKING AFTER YOUR SKIN ON ROACUTANNE

Wash your face with a low irritant moisturising soap such as Dove, Liquid Neutrogena for dry skin, cetaphil facial wash on acne prone skin or QV wash.

You may need to use a moisturising cream to dry areas. Try to use a relatively low oil moisturiser.

If you develop itchy pink rashes this is usually dermatitis and you may need some steroid cream to settle it down if moisturisers are no doing the job. Hydrocortisone cream is available without a script.

Dry lips are the main problem noticed by patients. A lip balm called AVENE or QV is good to use. Vaseline or other lip balms can be used. Carry a lip balm with you to use frequently during the day. These are available from chemists. If your lips are very bad Kenalog orabase Ointment on prescription is used.

Many cosmetics promote acne therefore if you use makeup use an oil free or non-comedogenic one. They can be more expensive, however most of the major cosmetic manufacturers produce a range of non-comedogenic cosmetics like Neutrogena or Clinique

Sunscreens which are cream based can promote acne and you will need to wear a sunscreen regularly while on Isotretinoin.” Cetaphil sunscreen with moisturiser “or “Ego daily face “or “Hamilton every day face” sunscreen is a good one to use as it tends not to aggravate acne. It is not water resistant though and if you need a water resistant one “milk” formulations are best.

If dry eyes occur use a simple eye lubricant from the chemist regularly. If this does not solve the problem you must mention this to your doctor as a more serious problem may be occurring. You may need to stop using contact lenses.

Nose bleeds are best treated by applying some vaseline to the inside of your nose with a cotton bud regularly. If you nose bleeds or is very crusty an antibiotic ointment may be needed on prescription.

Avoid excessive alcohol consumption

This may all sound too daunting after reading this information.

You must remember that the main side effect noted is dryness and this is generally easily managed.

All other side effects are uncommon, transient or improved with reducing the amount of Isotretinoin. Most patients only experience the dryness side effects. Between 5-15% of people may develop the other side effects.

Take the tablets with food and swallow whole, do not chew them

Most people are on between 1 and 3 tablets a day. Stay on this dose until you are seen by your Doctor again and depending on how you are going your dose may be increased. If you develop side effects you can reduce the dose yourself to see if they settle down.

Make an appointment to see your Doctor 4-5 weeks after starting Isotretinoin. You will need to have another blood test a few days before seeing them.

Girls should start isotretinoin when they get their menstrual period and after they have had a pregnancy test 1-2 weeks before starting to ensure they are not pregnant. If you are sexually active you will need to go on the contraceptive pill as this is the best form of contraception. This can be organized through your local Doctor, as you will need to answer questions about your health and have your blood pressure checked before starting the pill. If you are not willing to go on the pill then total abstinence from sex is recommended or visit family planning or your GP to speak to them about the safest forms of contraception. If you fall pregnant while on isotretinoin you have a very high chance of a birth deformity and will probably need an abortion.