Roaccutane (isotretinoin) is a vitamin A derivative, which has been on the market for almost 30 years. It is an extremely effective treatment for severe nodular-cystic acne, a condition where almost no other treatment will work. Roaccutane is also indicated for less severe acne, not responding to at least six months of appropriate oral and topical treatments (see Table 1). Not only will Roaccutane clear severe acne, it usually cures acne permanently in a majority of patients who complete a course.

Roaccutane works by shrinking the pilosebaceous unit (usually permanently) thus reducing the oiliness of the skin and comedones (blackheads and whiteheads). This leads to less bacterial overgrowth within the pilosebaceous unit. Roaccutane also has a powerful anti-inflammatory effect on the acne. Because Roaccutane works on all the levels in the pathogenesis of acne, it can be used as a monotherapy and no topical acne treatments are required.

The summary of product characteristics states: “isotretinoin should only be prescribed by or under the supervision of physicians with experience in the use of systemic retinoids for the treatment of severe acne and a full understanding of the risks of isotretinoin therapy and monitoring requirements”. This usually means that only doctors who have worked in a dermatology department for at least six to 12 months would have the experience required to prescribe it.

Roaccutane is highly teratogenic and so a hormonal contraceptive is compulsory for all women of childbearing age, even those who are not currently sexually active (young teenagers, nuns, etc). For those women who are sexually active, two methods of contraception should be used for one month before, throughout and for at least one month after completing a course of Roaccutane (eg, the oral contraceptive pill and condoms).

Another difficulty when prescribing Roaccutane is that there are unconfirmed reports that it may cause mood disorders, including depression and suicidal behaviour in some patients, especially young men. However, large controlled clinical studies have not been able to prove this. On the contrary, some groups such as the Acne Support Group in the United Kingdom feel that it is the acne itself and not the treatment that may cause depression. They feel that by treating the acne (be it with Roaccutane or other less potent therapies) the patient’s mood usually improves, particularly if they have had severe acne.

I usually tell all patients (and their parents if they are under the age of 18) that Roaccutane may cause mood disorders and depression and I instruct them to contact me immediately if they have any concerns or worries (see Table 2). I would not prescribe Roaccutane to somebody who has a history of depression.

I also advise all patients to keep alcohol to a minimum and in young men I try to get them to agree to avoid alcohol and other psychoactive drugs altogether while on Roaccutane. I do not prescribe Roaccutane around times of stress such as coming up to the Leaving Cert, before a wedding or a major birthday.

All patients on Roaccutane develop a dryness of the lips and mucous membranes (see Table 3). This is not a side-effect; this is how the drug works. Roaccutane shrinks down the oil-producing glands, thus drying out the skin and mucous membranes. Frequent use of a lip balm and 1% hydrocortisone ointment twice a day usually controls the dry lips. While the dryness of the mucous membranes usually settles after completing a course of Roaccutane, the dryness of the skin usually persists permanently in most patients.

All patients starting Roaccutane need fasting bloods.

Prescribing Roaccutane in general practice

Roaccutane should only be prescribed by those who can legally stand over their reasons to prescribe it and their experience in using it, writes David Buckley.

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(FBC, U&E, LFTs, glucose and lipid profile) before starting their treatment and monthly while on the treatment. I also repeat these bloods three months after finishing Roaccutane. I rarely see any problems with the blood tests apart from a transient increase in cholesterol and triglycerides in some patients, which reverts to its pre-Roaccutane levels after finishing a course of the drug.

Women of childbearing age also need a pregnancy test before starting Roaccutane, during the treatment and five weeks after completing a course of Roaccutane. Women can only be prescribed the drug one month at a time (no repeat prescriptions) and have to fill their prescription within seven days of it being issued. Roaccutane is contraindicated in breastfeeding mothers.

I insist that all patients who are going on Roaccutane must sign a consent form, informing them that it may cause mood disorders and depression and that they are to report to me immediately if they have any problems. I also get all women to sign a consent form agreeing to avoid pregnancy for one month before, throughout and one month after completing the course of Roaccutane. For children less than 18 years of age, a parent or legal guardian has to sign the consent form in the presence of the child. I usually keep clinical photographs before and after completing the course of Roaccutane.

The dose of Roaccutane is usually 0.5mg/kg/day to be taken in one or two divided doses with food. If there is a poor response and not too many side-effects after one or two months, the dose can be increased to 1mg per kilogram per day. Roaccutane is continued until all or almost all the spots have cleared up. A course usually lasts four to six months but can take up to nine months in some severe cases, especially if there is extensive acne on the back and chest.

Roaccutane always clears acne and in approximately 75% of patients who complete a course, their acne is permanently cured. The other 25% may develop a relapse of their acne a few months or a few years later. In general, patients are less tolerant of even mild acne after completing a course of Roaccutane which has resulted in a period of clear skin.

However, if the acne relapses after the course of Roaccutane, it is usually less severe than the original acne and often responds to simple topical treatments or a combination of topical and standard oral therapies. Some patients may develop more severe acne post-Roaccutane that may require a second course.

Patients should avoid laser treatment, chemical peels and wax epilation during treatment and for at least six months after completing a course of Roaccutane.

Since pregnancy prevention and psychiatric assessment are the most crucial parts of managing patients on Roaccutane, a GP with a special interest in dermatology with experience in psychiatry and family planning should be the ideal person to prescribe this drug. However, the threat of litigation is very high and so Roaccutane should only be prescribed by those who can stand over their reasons to prescribe it and their experience in using Roaccutane in a court of law.

David Buckley is in practice at The Ashe Street Clinic, Tralee, Co Kerry

References on request