PATIENT INFORMATION: ORAL PUVA TREATMENT OF PSORIASIS AND OTHER DISORDERS

Psoriasis is a chronic skin disorder in which there is an abnormally rapid multiplication of the cells of the outermost part of the skin (the epidermis). The precise cause of psoriasis still unknown.

A treatment called psoralen photochemotherapy involves taking psoralen by mouth 8-methoxypsoralen (also known as methoxsalen or 8-MOP), followed by exposure to high intensity long-wave ultraviolet light, known as UVA. Oral 8-methoxypsoralen in combination with high-intensity long-wave UV light has been approved since 1982 by the FDA for use in the treatment of severe psoriasis. Trisoralen by mouth followed by sunlight exposure, and Trisoralen or methoxsalen plus artificial UVA have been available since the 1940s for the treatment of vitiligo, a skin disease characterized by a patchy loss of pigment in the skin. PUVA therapy has also been shown to be effective for other skin disorders on an investigational basis. Some of these include mycosis fungoides, urticaria pigmentosa, lichen planus, polymorphous light eruption, alopecia areata, atopic dermatitis, and other forms of eczema.

PUVA treatment of psoriasis is effective in most individuals within approximately 25 treatments given 2-3 times a week. There are some patients, however, who are resistant to this therapy. Following significant improvement or clearing, a tapering maintenance schedule at less frequent intervals (once a week to every second or third week) is begun. PUVA is eventually discontinued. The length of remission following clearing by PUVA therapy is variable and may last several months to a year or more.

The crystalline form of psoralen (Oxsoralen) reaches the highest concentration in the skin within 2-3 hours after oral ingestion. If it is activated at that time by UVA, it will have its maximum possible effect. The development of a liquid form of 8-methoxypsoralen dispensed in a gelatin capsule (Oxsoralen-Ultra) has increased the effectiveness of PUVA in some individuals. This form of the drug is more rapidly absorbed and results in higher peak levels within a shorter time after ingestion compared to the crystalline form of the drug. Patients taking Oxsoralen-Ultra should receive their UVA treatment with a 1 ¼ to 1 ½ hours after taking the capsules. It is extremely important that the same form of the medication is taken before each UVA treatment in order to avoid a sunburn-like reaction.

Precisely how PUVA works is not known. Its mechanism of action probably involves activation of psoralen by UVA light that inhibits the abnormally rapid multiplication of the cells is psoriatic skin. There are multiple mechanisms of action of PUVA, including effects on the skin immune system, which may explain its effectiveness in the treatment of a variety of different skin disorders.

SIDE EFFECTS AND PRECAUTIONS

Acute Sunburn-Like Reactions

During the day of taking the psoralen medication you will be sensitive to ultraviolet light. You must, therefore, avoid exposure to sunlight during the entire day of treatment, even sunlight filtered through window glass, by wearing protective clothing and using the recommended sunscreen (SPF 30 or greater, broad-spectrum type, please get our sunscreen brochure) on the face and other exposed areas of the body. You may also be more sensitive to sunlight on non-treatment days, and, thus, should avoid prolonged sun exposure which could result in a sunburn reaction.
Eye Protection

During UV exposure, you will be provided with special close-fitting goggles to prevent burns to the eyes. We are asking you to protect your eyes because experimental animals without eye protection developed cataracts. The risk of developing cataracts due to PUVA with appropriate eye protection is negligible.

Because psoralen may be present in the lens of the eye during the day of treatment, the following eye precautions are advised:

During day 1 of PUVA treatment, UVA blocking plastic wraparound spectacles should be worn while outdoors from time of ingestion of the drug until bedtime. While outdoors in dim light, either the above or clear UVA blocking spectacles should be worn. Do not attempt to drive in dim light while using dark glasses.

During day 2, either the plastic wraparounds or the clear UVA blocking spectacles should be worn the entire day. Shielding of the eye during day 1 is an absolute requirement, and on day 2 it should be encouraged, but is a relative requirement.

LONG TERM SIDE EFFECTS

Skin Cancer

Because there is substantial data that sunlight, especially UV light, causes skin cancer and “aging” of the skin in humans, the likelihood exists that such changes might occur in patients receiving PUVA treatments. In experimental animals, such as albino mice, PUVA has been reported to include skin cancer. In psoriasis patients treated with PUVA, there is an increased risk of skin cancer (squamous cell carcinomas), particularly in individuals with certain risk factors. These include a history of exposure to x-ray therapy, a personal or family history of previous skin cancer, and a history of sunburning easily and tanning poorly. The increased risk of squamous cell carcinoma following PUVA therapy is related to the cumulative dose and duration of therapy.

Other Side Effects

In addition to the acute toxic effect of a sunburn-like reaction and long-term increased risk of skin cancer and cataracts, other side effects of PUVA have occurred. Itching during the course of PUVA therapy is quite common. This symptom is usually related to dryness of the skin and is relieved by the frequent application of moisturizing creams or lotions. Nausea is an occasional complication that is minimized by taking the psoralen pills with food. Marked tanning of the skin following PUVA therapy is usual, even in persons who do not ordinarily tan well following sun exposure. Less common side effects include pigmentary skin changes such as freckling, as well as spotty loss of pigment in the skin, appearing as white vitiligo-like patches.

FURTHER PRECAUTIONS AND FOLLOW UP

Blood tests and urinalysis may be done initially, and thereafter as indicated, depending on your medical status. Studies have shown that there are no significant laboratory changes attributable to PUVA therapy. If any skin lesions occur during the course of PUVA therapy that are suspicious for skin cancer, you will be advised to have a skin biopsy, with further treatment pending the biopsy report.
Since the effects of methoxsalen on a fetus are unknown, we recommend that women use birth control measures while being treated. This should be discussed with your physician before beginning treatment. Men should protect the genital area with a UVA opaque material.

Other sources of UV light, artificial or natural (sunlight), should be avoided unless adequate protection is provided. You risk burning your skin if you are exposed to other light sources while being treated with PUVA.

Since a number of medications, either taken internally or applied to the skin can adversely interact with UV light, please consult your physician regarding other medications, pills, and drugs that you are taking, even if only irregularly. These comments also pertain to non-prescription, over the counter preparations.

Other forms of antipsoriatic therapy, such as tar, anthralin, and topical cortisone like drugs, should not be used unless prescribed by your physician. This limitation may explain why your psoriasis may worsen at the beginning of the PUVA therapy. Although most areas of psoriasis are eventually controlled with continued PUVA alone, combination therapy may occasionally be prescribed for certain resistant areas. You are definitely encouraged to use bland lubricating ointments. Those areas of the body shielded from light exposure, such as the scalp and skin folds, may continue to be treated with topical antipsoriatic preparations as prescribed by your physician.

As part of your initial PUVA evaluations, you may be asked to complete the following:

1. An eye examination performed by an ophthalmologist at the beginning treatment, and at follow up intervals as determined by your physician. The examination must include the following: (a) gross examination; (b) visual acuity; (c) slit-lam examination of cornea and lens, and (d) funduscopic examination of the retina.

2. The following laboratory tests at initiation of therapy, and thereafter as indicated (a) complete blood count with differential; (b) chemistry screening; (c) serum creatinine; (d) fluorescent antinuclear antibody, and (e) routine analysis.

Your physician would be pleased to discuss any further questions or concerns you may have regarding PUVA therapy.

SPECIFIC INSTRUCTIONS FOR PATIENTS RECEIVING (PUVA) THERAPY

Psoralen Ingestion

Take Oxsoralen in amount prescribed with 2-3 hours before scheduled PUVA treatment. If taking Oxsoralen-Ultra, take medication 1 ¼ to 1 ½ hours before scheduled treatment.

Medication should be taken with food or after eating, not on an empty stomach.

Sunlight Protection

Avoid exposure to sunlight from the time of ingestion of the psoralen medication during daylight hours on the day of treatment. Avoid sunbathing or excessive sun exposure on days when not taking the medication, as you may be more susceptible than usual to sunburn.

Should exposure to sunlight be unavoidable (driving with sun exposed hands and arms), golfing, or other outdoor activities, your skin should be protected with clothing including gloves, hat, as well as the use of SPF 30 or greater broad-spectrum sunscreen, which can be purchased at our office or at local drug stores.
without a prescription. A list of appropriate sunscreens can be obtained from your physician.

Eye Protection

During day 1 of PUVA treatment, UVA blocking plastic wraparound glasses should be worn while outdoors from time of ingestion of the drug until bedtime. While indoors or in dim light, either the above or clear UVA blocking glasses should be worn. However, you should not attempt to drive in dim light while using dark glasses.

During day 2, either the plastic wraparounds or the clear UVA blocking glasses should be worn the entire day. Shielding of the eye during the day 1 is an absolute requirement; on day 2 it is encouraged but is a relative requirement.

Additional Treatment

An oil bath may be taken prior to UVA exposure, and bland emollients may be applied lightly prior to treatment. You should not apply tar medications, including LCD, on your skin prior to treatment.

It may be necessary to frequently apply oils or lubricating lotions during the treatment course, since PUVA may cause skin dryness.

Since the effects of methoxsalen on a fetus are unknown, we advise that women use birth control measures during the course of PUVA therapy. PUVA is contraindicated in nursing women.

Side effects related to medication or treatment must be reported to the nurse or physician. Any new medication should also be reported, as certain medications such as tetracycline antibiotics, diuretics, and tranquilizers may cause increased sensitivity to UV light.

Administration of PUVA Treatment

It is necessary to avoid unintentional shielding of body folds and underarms. A sunburn-like reaction may appear at these sites if they are first exposed late in the course of therapy. The assistant will instruct you on the position to maintain in the light unit.

The face and/or hands will be shielded from PUVA if no psoriasis is present in these areas. Shielding of the male genital area is also necessary. Please wear sunscreen on normal, unaffected skin.

If it is difficult for you to remain standing for the duration of the treatment, inform the nurse so that you may have a rest period part way through. The door opens easily from the inside, in the event you may need to leave the unit during treatment. Ultraviolet opaque goggles must be regularly worn during each PUVA exposure.