ABSTRACT

Psoriasis, acne vulgaris and photoaging are common conditions. Tazarotene is a pro-drug of tazarotenic acid, a receptor-selective retinoid which binds to RARβ and RARγ and weakly to RARα. Tazarotenic acid does not interconvert to any other retinoids that could potentially activate other retinoid receptors. In psoriasis, tazarotene normalizes keratinocyte differentiation, reverses keratinocyte hyperproliferation and has anti-inflammatory effects. In acne vulgaris, the abnormal desquamation of the follicular epithelium is normalized. In October 2001, the US FDA approved Tazorac cream 0.1% (tazarotene, Allergan) for the treatment of acne vulgaris. Since 1997, Tazorac gel (0.05% and 0.1%) has been available for the treatment of stable plaque psoriasis and the 0.1% gel is also indicated for the treatment of mild-to-moderately severe facial acne vulgaris. Tazorac cream (0.05% and 0.1%) was approved by the US FDA in 2000 for the treatment of plaque psoriasis. Approval by the US FDA and TPP – Canada is expected for the indication of photoaging sometime in 2002.

Tazarotene is efficacious as monotherapy, but is more commonly used in combination with phototherapy or with a topical corticosteroid in order to enhance efficacy and tolerability. Adjunctive use of a mid or high-potency steroid results in greater reductions of overall disease severity, plaque elevation and adverse events (see Table 1).

Rebound does not appear to be a problem. Epidermal atrophy induced by steroids can also be minimized by tazarotene. The reduction of epidermal thickness was only 28% when tazarotene was used in conjunction with diflorasone diacetate 0.05% compared to 43% when the steroid was used alone. Use of the 0.1% gel once daily in combination with mometasone furoate 0.1% cream once daily is more efficacious than twice daily calcipotriol ointment or twice daily mometasone furoate 0.1% cream. Superior maintenance of remission was seen with thrice weekly tazarotene 0.1% gel used in conjunction with twice weekly clobetasol propionate 0.05% ointment than when the vehicle was used alone.

Psoriasis

Psoriasis affects approximately 2% of the population. Plaque psoriasis, the most common variant, is characterized by well-defined erythematous scaly plaques, with or without associated nail disease and arthritis. In most patients, the disease is localized and amenable to topical therapy.

Acne vulgaris

Approximately 95% of the population suffers at some point in their lifetime from acne vulgaris. Papules, pustules, closed and open comedones, cysts and scarring may be seen. Although more common in teenage years, it may persist into the fourth and fifth
decades. Comparative clinical trials have shown that once daily 0.1% tazarotene gel is more efficacious than Retin A® 0.025% gel, Retin A Micro® 0.1% and Differin® gel and that alternate day use was as efficacious as once daily Differin® gel (see Table 3). Greater global improvement was noted when tazarotene 0.1% gel was used once daily in combination with 1% clindamycin phosphate once daily. This combination and the combination of tazarotene 0.1% gel + erythromycin/benzoyl peroxide gel once daily were significantly more efficacious than twice daily 1% clindamycin phosphate lotion.

Comparators Results

| Tazarotene 0.1% gel +: | • There was a lower median time to reach 50% improvement with (2 weeks) or HIGH (3 weeks) vs. placebo (4 weeks) (p<0.05). |
| — Flucinolone acetonide 0.01% cream (LOW) vs. | • More patients showed 50% improvement at 12 weeks with MID (91%) or HIGH (95%) vs. placebo (80%) (p<0.05). |
| — Mometasone furoate 0.1% cream (MID) vs. | • There were fewer adverse events with MID or HIGH. |
| — Flucinolone 0.05% cream (HIGH) vs. | • No differences were seen between LOW and placebo. |
| — Placebo cream10 | |

Tazarotene 0.1% gel +:
- Flucinolone 0.05% vs.
- Mometasone furoate 0.1% vs.
- Dinflorasone diacetate 0.05% vs.
- Betamethasone dipropionate 0.05% cream vs.
- Fluticasone propionate 0.005% vs.
- Dinflorasone diacetate 0.05% cream11

| Tazarotene 0.1% gel q.d. + Mometasone furoate cream q.d. vs. Calcipotriol 0.005% ointment b.i.d.6 | There was a statistically significant greater global improvement and reduction of plaque elevation, scaling and erythema with betamethasone dipropionate 0.05% cream, mometasone furoate 0.1% ointment and dinflorasone diacetate 0.05% ointment compared to tazarotene monotherapy. |

| Tazarotene 0.1% gel q.d. + Mometasone furoate 0.1% cream q.d. vs. Mometasone furoate cream b.i.d.7 | The tazarotene + mometasone furoate group had significantly greater and more rapid efficacy, and a more prolonged effect post-treatment. |

| Tazarotene 0.1% gel thrice weekly vs. | At 5 months, 73% on tazarotene/clobetasol, 47% on tazarotene and 19% on vehicle had retained at least a 50% improvement relative to baseline (p<0.05). |
| Tazarotene 0.1% gel thrice weekly vs. Calcipotriol 0.005% ointment b.i.d.8 | |
| Tazarotene 0.1% gel thrice weekly + clobetasol propionate 0.05% ointment twice weekly vs. vehicle after achieving at least 50% improvement8 | |

Table 1: Topical corticosteroid combination trials with tazarotene 0.1% gel.

Results of the phototherapy trials are shown in Table 2. In all studies, enhanced efficacy and a lowered incidence of irritation without additional phototoxicity were noted when tazarotene was used.

Phototherapy Results

| UVB broad band12 | To obtain 50% improvement: median cumulative UVB was reduced (390 mJ/cm² vs. 1644 mJ/cm²) (p<0.001) and less time was needed (25 days vs. 53 days) with tazarotene 0.1% gel once daily for 2 weeks, followed by thrice weekly UVB + tazarotene 0.1% gel compared to UVB monotherapy. |
| 311 UVB narrow band5 | There was a significantly greater reduction in psoriasis area and severity index (PASI) in 1/2 body treated with tazarotene 0.1% gel vs. 5% salicylic acid ointment 1 week before and during 3 weeks of 311 UVB. |
| 311 UVB narrow band13 | There was a greater reduction in PASI in the 1/2 body treated with tazarotene 0.1% gel (64%) vs. emollient (48%) (p<0.05). |
| Bath PUVA14 | There was a 76% decrease in PASI after 3 weeks in tazarotene 0.05% gel treated 1/2 body vs. 58% with vehicle (p<0.05). |

Table 2: Phototherapy trials with topical tazarotene

Photoaging
Clinical studies have shown that topical tazarotene 0.1% gel, 0.05% cream and 0.1% cream are more efficacious than the vehicle in reducing fine wrinkling (see Table 4). In a 24-week study involving 349 individuals, mottled hyperpigmentation and overall integrated assessment (OIA) of photodamage were improved with both cream formulations and 0.05% tretinoin cream when compared to the vehicle. There was a trend towards a faster response with 0.1% tazarotene cream when compared to
the 0.05% formulation. The 0.05% tazarotene and tretinoin groups had a similar proportion with at least 50% improvement, but at weeks 12 and 20, the 0.1% tazarotene group had a significantly greater proportion compared to the tretinoin group.

Side effects
Local cutaneous irritation including burning, itching, erythema, peeling or dryness occurs in approximately one-quarter of patients. In clinical trials, the severity was usually mild-to-moderate.

Drug interactions
Additional dryness might occur with other dermatologic medications or cosmetics with a strong drying effect.

How to use
Patient education is important in order to minimize the potential for irritation. A small amount of tazarotene should be applied to dry skin, typically at night. However, since the product is photostable, it can be used in the morning. The cream and gel do not stain clothing and rub in well. In the treatment of psoriasis, only the areas affected with psoriasis are treated since use on uninvolved skin may be associated with irritation. Use of a cotton-tipped applicator and protection of the surrounding skin with petrolatum may help minimize use on unaffected skin. In acne, the entire affected area (not just lesions) is treated in the hope of preventing microcomedo formation.

In order to minimize irritation, treatment can be initiated with the 0.05% cream and stepped up as tolerated. Scalp and nail psoriasis are preferentially treated with the gel formulation. Alternate day and short contact treatment (30 seconds-5 minutes) can also be considered. With time, most patients are able to tolerate once daily treatment, but may occasionally need to skip an application. In the winter and in dry climates, emollients may reduce dryness and enhance tolerance. They can be applied immediately after washing with a mild cleanser prior to application of tazarotene, or at another time of day. Application immediately after applying tazarotene might result in inadvertent spread of tazarotene. In the treatment of psoriasis and acne vulgaris, combination therapy should be considered as a means of increasing efficacy and tolerability.

<table>
<thead>
<tr>
<th>Comparators</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tazarotene 0.1% gel q.d. vs. Retin A® gel q.d.¹⁵ 0.025%</td>
<td>Tazarotene was more efficacious in reducing open comedo count (65% vs. 44%, p=0.03), total noninflammatory lesion count (55% vs. 42% p=0.04) and total inflammatory lesion count (54% vs. 44% NS)</td>
</tr>
<tr>
<td>Tazarotene 0.1% gel q.d. vs. Retin A Micro® 0.1% q.d.¹⁶</td>
<td>There were statistically significant reductions in overall disease severity (36% vs. 26%, p=0.02), global response scores (2.80 vs. 3.35, p=0.02), and noninflammatory lesions (60% vs. 38%, p=0.02) with tazarotene.</td>
</tr>
<tr>
<td>Tazarotene 0.1% gel q.d. vs. Differin® Gel q.d.¹⁷</td>
<td>There was a greater reduction with tazarotene when compared to adapalene in mean global response score (2.38 vs. 3.41 at 12 weeks, p=0.0001), overall disease severity (44% vs. 24%, p&lt;0.0001), noninflammatory lesions (71% vs. 48%, p&lt;0.0001), inflammatory lesions (70% vs. 55%, p=0.0002) and those with at least 50% improvement (78% vs. 52%, p=0.002).</td>
</tr>
<tr>
<td>Tazarotene 0.1% gel q.d. vs. Differin® Gel q.d.¹⁸</td>
<td>There were no significant differences in efficacy.</td>
</tr>
<tr>
<td>Tazarotene 0.1% gel q.d. vs. Tazarotene 0.1% gel q.d. + 1% clindamycin phosphate q.d. vs. Tazarotene 0.1% gel q.d. + benzoyl peroxide gel q.d. vs. 1% clindamycin phosphate lotion. Tazarotene 0.1% gel + Erythromycin 3%/Benzoyl Peroxide 5% gel q.d. vs. Clindamycin Phosphate 1% q.d.¹⁹</td>
<td>There was significantly greater global improvement with tazarotene 0.1% gel + 1% clindamycin phosphate than with tazarotene monotherapy or clindamycin monotherapy. Tazarotene 0.1% gel + erythromycin/benzoyl peroxide gel once daily was significantly more efficacious than twice daily</td>
</tr>
</tbody>
</table>

Table 3: Acne vulgaris comparative trials

<table>
<thead>
<tr>
<th>Comparators</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tazarotene 0.1% gel q.d. vs. vehicle q.d.²⁰</td>
<td>Tazarotene 0.1% gel was more efficacious than vehicle after 12 weeks in reduction of fine wrinkling and skin roughness on forearm skin (p=0.008).</td>
</tr>
<tr>
<td>Tazarotene 0.05% cream q.d. vs. Tazarotene 0.1% cream q.d. vs. tretinoin 0.05% cream q.d. vs. vehicle q.d.²¹</td>
<td>Tazarotene 0.05%, tazarotene 0.1% and tretinoin 0.05% creams significantly improved mottled hyperpigmentation, fine wrinkles and OIA compared to vehicle (67% on 0.1% tazarotene, 52% on 0.05% tazarotene and 55% on tretinoin 0.05% cream had at least 50% improvement at week 24).</td>
</tr>
</tbody>
</table>

Table 4: Photoaging studies
Contraceptive counseling should be given to women of childbearing potential before topical tazarotene is used. Although absorption is minimal, it should not be used by pregnant women since systemic tazarotene is teratogenic.

**Conclusions**

Topical tazarotene is very efficacious in the treatment of psoriasis, acne and photoaging. It is the most potent comedolytic topical retinoid currently available. Combination therapy with corticosteroids or phototherapy in psoriasis, or antibiotics in acne vulgaris, can enhance efficacy and tolerance. Irritation can be minimized with patient education, and use of the 0.05% cream, on alternate day and short-contact regimens.

**References**

15. Webster GF, Berson D, Stein LF, Fivenson DP, Tanghetti EA, Ling M. Efficacy and tolerability of once-daily tazarotene 0.1% gel versus once-daily tretinoin 0.025% gel in the treatment of facial acne vulgaris: a randomized trial. *Cutis* 67(6 Suppl):4-9 (2001 Jun).
18. Leyden J, Lowe N, Kakita L, Draelos Z. Comparison of treatment of acne vulgaris with alternate-day applications of tazarotene 0.1% gel and once-daily applications of adapalene 0.1% gel: a randomized trial. *Cutis* 67(6 Suppl):10-6 (2001 Jun).
21. Kang S, Leydon JJ, Lowe NJ, et al. Tazarotene cream for the treatment of facial photodamage: a multicenter, investigator-masked, randomized, vehicle-controlled, parallel comparison of 0.01%, 0.025%, 0.05%, and 0.1% tazarotene creams with 0.05% tretinoin emollient cream applied once daily for 24 weeks. *Arch Dermatol* 137(12):1597-604 (2001 Dec).

**INDUSTRY NEWS**

Roche Initiates an Enhanced Pregnancy Prevention Program to Prevent Accutane®-Exposed Pregnancies

In January 2002, Hoffmann-LaRoche, working closely with the US FDA distributed an enhanced version of their Pregnancy Prevention Program for Women on Accutane® to more than 375,000 dermatologists, primary care prescribers and pharmacists in the US. The program is called S.M.A.R.T. (System to Manage Accutane® Related Teratogenicity). It involves the prescriber, pharmacist and patient to ensure that female patients are not pregnant when they begin taking Accutane® and that they do not become pregnant while taking the medication and for one month after stopping treatment. An innovative component of the program is the use of yellow self-adhesive Accutane® Qualifications Stickers, which prescribers will apply to all Accutane® prescriptions.

To receive the first Accutane® prescription, the female patient will be required to meet four qualifications:

1. Have two negative pregnancy tests – the first as a screening test and the second as a confirmation test that will be administered during the first 5 days of her next menstrual period.
2. Select and commit to using two effective forms of birth control simultaneously one month prior to treatment, during treatment and for one month after stopping treatment.
3. Read and sign an informed consent agreement explaining the risk of potential birth defects associated with Accutane®.
4. Learn about and be encouraged to enroll in the Accutane® Survey, a system to track female Accutane® patients, learn about their experiences with pregnancy prevention efforts and determine their pregnancy status.

Each month the patient must have a negative pregnancy test and receive contraceptive counseling from the prescriber before receiving a new prescription. If the patient meets these qualifications, or is male, the prescriber will then write a prescription for a 1-month supply, affix one of the yellow Accutane® Qualification Stickers and date it. Prescriptions must be filled within 7 days of the qualification date on the sticker.

This program is being phased in and the deadline for compliance is April 10, 2002.

The S.M.A.R.T. program is only applicable for treating patients in the US. For other countries, including Canada, Roche has created uniquely tailored programs to address their distinctive health care needs.
Common Sense Dermatological Drug Suggestions
For Women Who Are Breast-feeding

C. Zip, MD, FRCPC
Department of Medicine, University of Calgary, Calgary, Alberta, Canada

ABSTRACT

Use of medications by breast-feeding mothers is not uncommon. When prescribing a medication to a nursing mother, the physician must weigh the potential risk of exposing the infant to the medication or the risks of not breast-feeding against the benefits of the medication to the mother. Information regarding the safety of common dermatological medications during lactation will be reviewed. Based on this information, treatment recommendations will be made.

Key Words: breast-feeding, antimicrobials, antihistimines, immunomodulators, antipsoriatics, steroids, scabicides, anti-acne agents

Breast-feeding provides optimal nutrition in the first 6 months of life. Well documented benefits of breast-feeding include a decreased incidence of infantile diarrhea and infection. Other studies show a possible protective affect against sudden infant death syndrome, insulin dependent diabetes mellitus, Crohn’s disease, ulcerative colitis, lymphoma, and allergic disorders. The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for the first six months of life, continuing to a year or beyond with the addition of solid food at 6 months of age. In Canada, approximately 80% of new mothers initiate breast-feeding, while 30-40% are still nursing 6 months postpartum. Corresponding US figures are 64% and 29%, respectively.

The use of prescription and over-the-counter (OTC) medications is common for nursing mothers. In one study of 14,000 pregnant or breastfeeding women, 79% of them took at least one medication, while on average, 3.3 drugs were taken while breastfeeding. Fortunately, severe adverse effects resulting from the presence of common medications in breast milk are uncommon. Of 838 infants exposed to medications through breast milk, 11% experienced minor reactions, and no serious reactions requiring medical attention or cessation of breastfeeding occurred. The adverse reactions that did occur were consistent with the known pharmacological affects of the causative agent.

Transfer of Medications into Breast Milk

A number of factors determine the passage of a drug into breast milk. These include characteristics of the mother, the infant and the drug itself. In general, drugs given to a nursing mother reach the infant in much lower concentrations than those given to a pregnant woman reach the fetus.

Antimicrobials

Penicillins and cephalosporins are present only in trace amounts in breast milk, and are compatible with breast-feeding. Their use is associated with a remote risk of alterations in gastrointestinal flora causing diarrhea and allergic sensitization of the infant. Erythromycin is excreted into breast milk, but no adverse effects in infants exposed to this drug in breast milk have been reported, and it is considered compatible with breastfeeding by the AAP. Caution may be in order in when prescribing erythromycin to lactating mothers of newborns however, because of recent reports of pyloric stenosis in neonates treated with erythromycin. It has been reported that the calcium present in breast milk may inhibit absorption of the small amount of tetracycline, however, use of tetracycline while breastfeeding is not advised, because the threshold for its affect on teeth and bone is unknown. Topical clindamycin is partially absorbed through the skin and small amounts may pass into breast milk. No problems have been reported in nursing infants with maternal use of topical clindamycin, although bloody diarrhea was reported in an infant of a mother on intravenous clindamycin. No adverse effects on the infant have been reported with use of topical metronidazole during lactation, however the manufacturer advises against its use while breast-feeding. Acyclovir is considered safe during breast-feeding. Experience with the use of valacyclovir and famciclovir during human lactation is lacking.

Antihistamines

Small amounts of antihistamines are excreted in breast milk. Their use is not recommended during breast-feeding because infants may be more susceptible to their adverse effects, particularly drowsiness and irritability. Antihistamines may also reduce milk production in some women.

Immunomodulators

Both cyclosporine and methotrexate are excreted into breast milk, and considered contraindicated during breast-feeding by the AAP because of the possibility of immunosuppression, neutropenia, carcinogenesis and unknown affects on growth. Hydroxychloroquine is excreted in small amounts in breast milk and because of its slow elimination rate and potential to accumulate to toxic levels in infants, caution is advised with daily use.
dosing. The AAP, however, considers hydroxychloroquine to be compatible with breast-feeding. Tacrolimus is excreted in human milk. Topical tacrolimus is not recommended by the manufacturer during breastfeeding, because of the potential for systemic absorption with topical use. The AAP does not rate tacrolimus.

**Antipsoriatrics**

It is not known whether calcipotriol is excreted into breast milk. The manufacturer recommends its use only if the anticipated benefits outweigh the potential risks. Methoxsalen excretion in human milk is also unknown and although there are no reports of adverse effects with its use during lactation, the manufacturer recommends use only when the probable benefits outweigh the potential risks. Briggs recommends that breast-feeding be interrupted for at least 24 hours after administration of the drug because of its photosensitizing affect.

**Steroids**

Trace amounts of prednisone and its metabolite prednisolone are excreted in breast milk. The AAP considers prednisone to be compatible with breastfeeding. Hypertension was reported in the infant of a woman who used a corticosteroid on the nipples. Use of topical corticosteroids on the breasts prior to nursing should be avoided.

Because estrogen decreases the quantity and protein content of breast milk, the use of combination oral contraceptive pills should be avoided whenever possible in lactating mothers, especially in the first two months postpartum.

**Scabicides**

It is not known if permethrin is excreted in human milk. Citing evidence of teratogenicity in animals, the manufacturer recommends temporary discontinuation of nursing or avoidance during lactation. Anderson considers its use to be safe during lactation.

**Analgesics**

Significant salicylate levels have been found in breast-fed neonates of mothers taking salicylates, raising concerns about metabolic acidosis, bleeding, altered pulmonary circulation and Reye’s syndrome. There is one report of salicylate intoxication in an infant exposed through her mother’s milk. The AAP recommends that it be used with caution in nursing mothers. Widespread use of topical salicylic acid should be avoided because of the potential for significant systemic absorption. Of the nonsteroidal anti-inflammatories, ibuprofen and flurbiprofen have the best documentation of safety during lactation because they do not enter breast milk in significant quantities. The AAP considers ibuprofen, indomethacin, and naprosyn to be compatible with breast-feeding. There is one case report of seizures in an infant exposed to indomethacin through breast milk.

**Antiacne Agents**

There have been no reports of adverse effects from use of topical benzoyl peroxide and topical tretinoin during lactation. It is not known whether adapalene or tazarotene pass into breast milk. The manufacturers recommend caution with their use during

<table>
<thead>
<tr>
<th>Class of Medication</th>
<th>Choices Compatible with Breast-Feeding</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Antibiotics</td>
<td>Penicillins, Cephalosporins, Erythromycin (caution with neonates), Topical clindamycin, Topical metronidazole</td>
<td>Possibility of diarrhea, thrush and allergic sensitization of the infant</td>
</tr>
<tr>
<td>Antivirals</td>
<td>Acyclovir</td>
<td>Considered safe during breastfeeding</td>
</tr>
<tr>
<td>Antifungals</td>
<td>Fluconazole</td>
<td>Manufacturer does not recommend its use during lactation.</td>
</tr>
<tr>
<td>Antihistamines</td>
<td>None</td>
<td>Infants may be more susceptible to their adverse effects</td>
</tr>
<tr>
<td>Immunomodulators</td>
<td>Hydroxychloroquine</td>
<td>Methotrexate and cyclosporine are not recommended</td>
</tr>
<tr>
<td>Antipsoriatrics</td>
<td>Calcipotriol</td>
<td>No reports of adverse effects</td>
</tr>
<tr>
<td>Steroids</td>
<td>Prednisone</td>
<td>Trace amounts of prednisone are present in breast milk. Avoid use of topical corticosteroids on breasts prior to nursing. Delay use until milk production established; may reduce milk production.</td>
</tr>
<tr>
<td>Scabicides</td>
<td>Permethrin</td>
<td>Probably safe; consider temporary discontinuation of breastfeeding.</td>
</tr>
<tr>
<td>Analgesics</td>
<td>Ibuprofen, Acetaminophen</td>
<td>Ibuprofen does not enter breast milk in significant amounts.</td>
</tr>
<tr>
<td>Antiacne</td>
<td>Benzoyl peroxide, Topical tretinoin</td>
<td>No reports of adverse effects</td>
</tr>
</tbody>
</table>

Table 1: Compatibility of some dermatologic drugs during breastfeeding.
lactation.36,37 Spironolactone may pass into breast milk, but has not been reported to cause problems in nursing babies.19 The AAP considered spironolactone to be compatible with breast-feeding,15 although its use during lactation is not recommended by the manufacturer.38

Conclusion
When considering a medication for a lactating mother, the benefits of breast-feeding need to be weighed against the potential risk of exposure of the infant to the drug in question. For the majority of dermatological conditions, alternatives that are compatible with breast-feeding are available, or treatment can be safely postponed until lactation is completed.

References
32. Permethin product monograph, GlaxoSmithKline, Mississauga, ON, Canada, 2002.
37. Tazarotene product monograph, Allergan, Markham, ON, Canada, 2001.

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7
<table>
<thead>
<tr>
<th>Class</th>
<th>Name/Company</th>
<th>Approval Dates and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antiviral Agent</strong></td>
<td>Naturally-Derived Alpha Interferon</td>
<td>The Swedish Regulatory Authorities approved expanded use in January 2002, to include the treatment of patients afflicted with any and all diseases in which patients were or became resistant to treatments using recombinant (synthetic) interferon. Recombinant interferons usually contain only one subtype of interferon as compared to multiple subtypes in naturally derived interferon, which is produced by human white blood cells.</td>
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<tr>
<td></td>
<td>Viragen</td>
<td></td>
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<tr>
<td>HIV/AIDS</td>
<td>Efavirenz</td>
<td>The US FDA approved a new one-tablet 600mg. formulation in February 2002, of this non-nucleoside reverse transcriptase inhibitor used in combination treatment for HIV. The new formulation will provide doctors with the option of prescribing one 600mg. tablet once daily instead of three 200mg. capsules once daily.</td>
</tr>
<tr>
<td>Oncologic Agent</td>
<td>HSPPC-96</td>
<td>The US FDA granted fast-track designation in February 2002, for this cancer vaccine for the treatment of metastatic melanoma.</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>Tenofor Disoproxil Fumarate Viread® Gilead Sciences</td>
<td>The EMEA granted marketing approval in all 15 member states of the European Union in February 2002, for use in combination with other antiretroviral agents for the treatment of HIV infection in patients who are experiencing early virological failure.</td>
</tr>
<tr>
<td>Antihistamine</td>
<td>Desloratidine Clarinex® 5mg. Tablets Schering-Plough</td>
<td>The US FDA approved additional indications for this antihistamine in February 2002, to treat chronic idiopathic urticaria and symptoms of allergies caused by indoor and outdoor allergens in adults and children &gt;12 years of age.</td>
</tr>
</tbody>
</table>

**Drug News**

**HIV/AIDS**

Many scientists have believed that HIV acts to deplete its primary target, CD4+ T-cells by blocking new T-cell production. According to a report from the US National Institutes of Health, two independent studies demonstrated that HIV does not block such production, but acts to accelerate the division of existing T-cells. Consequently, the increases in CD4+ T-cell counts seen following highly active antiretroviral therapy (HAART) are not due to a boost in the production of new T-cells. Instead, they are caused by a slowdown in the loss of existing T-cells.

**Sunscreens**

According to an article published in the *Journal of the American Academy of Dermatology* sunscreen should be reapplied 15-30 minutes after sun exposure begins for maximum benefit. An individual who does this will have 15-40% less exposure to ultraviolet rays than someone who waits for 2 hours before reapplying sunscreen.