CPMA
Canadian Podiatric Medical Association Newsletter
September 2004

# MESSAGE FROM THE OUTGOING PRESIDENT

Dear Colleagues:

As you may be aware, my term as President of the Canadian Podiatric Medical Association came to an end at the spring 2004 meeting in Quebec. It has been an honour and a pleasure to serve the membership over the past five years. I believe that many of our goals have been met and I think that the future looks brighter for podiatric medicine in Canada.

I would like to thank my executives for all their support and devotion. I would also like to thank our Administrative Assistant Jocelyn Minton for all her hard work, dedication and commitment to the job. Most importantly, I would like to thank my wonderful wife Ruth for her understanding, support and sacrifice of her time during my term. Even though I am stepping down, I will remain actively involved as a resource, mentor and adviser to our incoming President, Mario Turanovic.

Over the past few years, many of our objectives have been met. For example, the inclusion of the Manitoba Podiatry Association into the C.P.M.A. became a reality last year. Sandy Todd, D.Pod. M. and the 17 other members who joined the C.P.M.A. are dedicated to the high standard of podiatric care and will be an asset to this association and to the profession of podiatry. The new Podiatry Act in Manitoba, with its increased scope of practice, will attract future podiatrists to that province. While we were not successful in bringing in the Saskatchewan Association into the C.P.M.A., I am quite confident that the "winds of change are in the air," especially since final passage of their new Podiatry Act is pending.

Our Group Health and Dental Plan is up and running with thanks to the efforts of Joel Finklestein of Finklestein and Associates (a.k.a. Finklestein Financial Services). The premiums that Joel secured for us were very reasonable and will be subject to a yearly review. Please note that the anniversary date of the policy will be October 31st yearly. To date, close to 80 members and their staff have signed on. Our Group Malpractice Insurance Policy has seen some premium increases this year consistent with other insurances. All provinces are fully participating in this policy.

Additionally, our long-standing effort to update our CPMA bylaws has been accomplished. While we hoped to ratify the bylaws at the April 2004 meeting, this issue was deferred pending review by our lawyer. I would like to thank Abe Osbourne, D.P.M. and Jocelyn Minton for their tireless efforts on this project.

On the international front, work continues with the International Federation of Podiatrists (F.I.P.). Two more countries, Ireland and Italy, have been voted into the F.I.P and Ronald Lepow, D.P.M., formally a Past President of the A.P.M.A., serves as the F.I.P. President. I am serving as the First Chairman of the World Foot Health Awareness Month Committee (W.F.H.A.M), and our primary objective is focused on increasing public awareness of podiatric medicine.

Finally, I would like to thank the Ordre des podiatres du Quebec and especially Christine Morin for the fine job of organizing the 2004 C.P.M.A. Annual General Meeting and the Provincial Scientific Conference. We are all proud of the hard work that Dr. Allart and his Association have done over the last 10 years with respect to the creation of the first Canadian School of Podiatric Medicine at the University of Quebec in Trois Rivieres (U.Q.T.R.). Dr. Allart and I both know how much effort and dedication it has taken to make this dream come true. I hope that this momentous event will serve to be a catalyst for other provinces in Canada to move in this same direction.

*"Membership Does Have Its Benefits"*

Fraternally,
*Robert C. Chelin, D.P.M.*
*Past President*

*Canadian Podiatric Medical Association*

# MESSAGE FROM THE INCOMING PRESIDENT

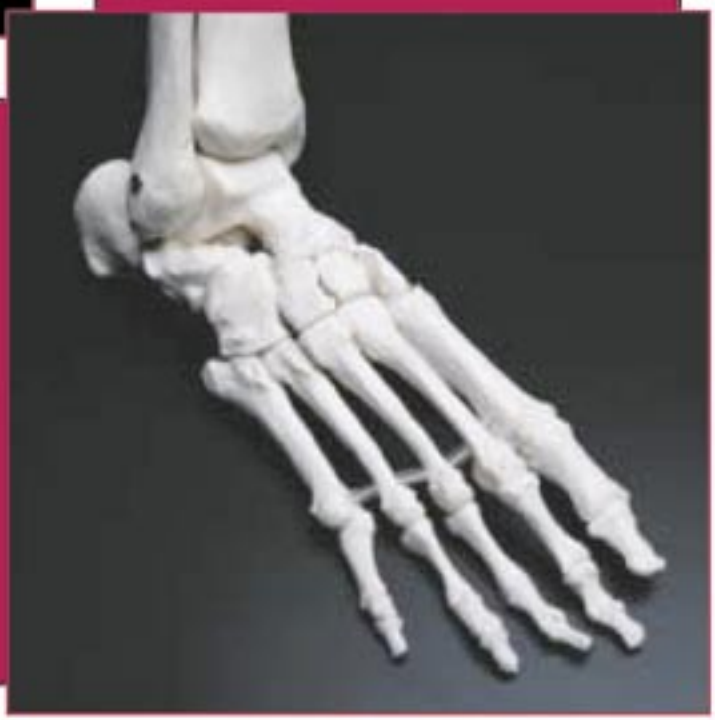
It is indeed my pleasure to step into the position of president of the CPMA. The work that Bob Chelin has done in the past five years has resulted in much progress on behalf of all our members. I hope to continue his efforts by increasing benefits for members and achieving greater awareness about podiatry – for the public, among colleagues in the medical profession, and especially for our patients.

As you may know, the prescribing narcotics issue is very dear to my heart. I am very pleased to be appointed to the National Advisory Committee on Expanding the Authority to Prescribe Controlled Substances, and will work hard to ensure that the existing omission of podiatrists in the federal Controlled Drugs and Substances Act is rectified. At a national level, we are also in a much better position now to dialogue with the federal government on changes needed in the podiatry profession. Additionally, I intend to provide whatever support I can to repeal the cap that currently exists for podiatry in Ontario.

Other key issues that I hope to successfully report on during my term as president include

*Cont'd page 3*

# A QUARTER OF ALL THE BONES IN YOUR BODY ARE IN YOUR FEET



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working towards a greater cohesiveness within our profession across Canada and encouraging non-legislation provinces to establish D.P.M. legislation within their province. In the past, bickering and differing viewpoints have only served to hurt our profession. The inconsistencies across provinces impede the quality standards of our profession. By working together, we can achieve much greater success.

We have already embarked upon a major revision of the CPMA website. The end result will be an easy to navigate website that contains information of relevance to our members. We are also including a section on the Seal of Approval program and our partners, and encourage you to speak to your suppliers about obtaining a Seal of Approval for their products. The funds from this program are used to enhance education and awareness about our profession, so it is in everyone's best interest to help this program grow.

I am also looking forward to hosting the 2005 CPMA Annual General Meeting in Lake Louise, Alberta in conjunction with the Region VII and the Alberta Podiatry Association Conference. I encourage all CPMA members to join us for a top-notch conference in a breathtakingly beautiful location. You will not be disappointed. Mark your calendar now to attend October 28-30, 2005 at the Fairmont Chateau Lake Louise. Details about the educational program are in the works and more information will be provided in the near future.

Most importantly, though, I hope to hear from you about what steps we can take to make the CPMA an even better association on behalf of our members. Please feel free to contact me via email at askus@podiatrycanada.org.

Sincerely,

*Mario G. Turanovic*, D.P.M.
*President*

*Canadian Podiatric Medical Association*

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# PRÉSENTATION AU CPMA

Programme universitaire en podiatrie à l'université du Québec à Trois-Rivières.

Le 10 novembre 2003, a été annoncé la création du premier programme universitaire francophone en podiatrie à l'Université du Québec à Trois-Rivières.

Les infrastructures dont dispose le Québec, combiné aux ressources du New York College of Podiatric Medecine, la plus ancienne faculté de podiatrie au monde, permettront de former des professionnels hautement compétents, et ce, dès septembre 2004. Par le fait même, ce programme universitaire contribuera à la qualité des services offerts à la population tout en réduisant les coûts du système de santé. Le Québec est appelé à devenir une plaque tournante en recherche et développement dans ce secteur d'expertise. Les retombées de ce programme rayonneront à l'échelle internationale et contribueront à créer des débouchés et de nombreux emplois dans les domaines universitaires et de la recherche et de la podiatrie.

La podiatrie devient aussi accessible que tous les autres programmes de doctorat de premier cycle au Québec et représente ainsi une solution durable à la pénurie de podiatres à laquelle fait face la province.

Les préparatifs vont bon train et en mars 2004, le Dr Michel Joubert, podiatre, a été nommé à titre de directeur de la faculté de podiatrie.

**"DOCTORAT EN MÉDECINE PODIATRIQUE "OU "DOCTORAT EN PODIATRIE "?**

Les représentants de l'Ordre des podiatres ont rencontrés, le 13 février dernier, les représentants de l'Office des professions.

Lors de cette rencontre, l'Ordre des podiatres a mis en lumière ses inquiétudes relatives à la désignation du diplôme à être décerné par l'Université du Québec à Trois-Rivières, et plus précisément, à la possibilité que le diplôme offert soit un « Doctorat en podiatrie » plutôt qu'un « Doctorat en médecine podiatrique ».

Il semble que le changement de désignation du diplôme envisagé découle d'une volonté d'uniformiser le titre du programme avec d'autres doctorats de 1er cycle, tels que ceux en chiropractie ou en optométrie. L'Ordre des podiatres est d'avis que, dans le cas de la podiatrie, ces exemples ne sont pas comparables, car nulle part en Amérique il est question d'un « Doctorat en médecine chiropratique » ou un « Doctorat en médecine optométrique » .

*Université de Québec à Trois-Rivières*

L'emploi de la désignation "Doctorat en médecine podiatrique" respecte le principe de l'uniformité en ce que cette désignation est conforme aux lois et règlements en vigueur et conforme à la pratique moderne de la podiatrie.

L'Ordre des podiatres craint que l'existence de deux catégories de diplômés, soit ceux détenant un diplôme américain ou canadien et ceux détenant un diplôme québécois, ne crée une confusion pour le public. De même, la création d'une nouvelle norme strictement québécoise aura des conséquences sur la mobilité de nos diplômés.

Les représentants de l'Office des professions ont porté une oreille très attentive aux inquiétudes de l'Ordre, et particulièrement à celles pouvant avoir un impact sur la protection du public.

L'École de podiatrie à l'U.Q.T.R. est un projet auquel l'Ordre des podiatres se dévoue entièrement. Nous souhaitons la coopération de tous afin de mener à bien ce projet.

Par ailleurs, l'Ordre des podiatres du Québec désapprouve l'initiative de Monsieur Sébastien Hains dans ce dossier. Son intervention et surtout l'implication des médias a entravé sérieusement le bon déroulement de ce projet.

**MÉDICAMENT**

En mars 2003, la liste de médicaments que les podiatres sont autorisés à prescrire a été mise à jour et les médicaments prescrits par les podiatres sont maintenant couverts par la RAMQ.

**ÉLECTIONS 2004**

Les membres suivants ont été élus par acclamation aux postes d'administrateurs pour un mandat d'une durée de trois (3) ans:

Michel Bourque
Serge Gaudreau
Patrice Roy

**RÈGLEMENT SUR L'INCORPORATION DES PROFESSIONNELS ET MODIFICATIONS AU CODE DE DÉONTOLOGIE**

En décembre 2003, nous souhaitions l'adoption de ces deux règlements pour janvier ou février 2004. Nous en sommes toujours au stade de la rédaction finale et nous travaillons activement à ce que les deux règlements soient adoptés le plus rapidement possible. Il semble cependant que l'étude par l'Office des professions des projets de règlements de la majorité des ordres professionnels ait été reportée au printemps. Nous attendons des nouvelles d'ici peu.

**NOUVEAUX MEMBRES**

L'Ordre des podiatres du Québec a accueilli en 2003-2004, quatres (4) nouveaux membres soit : Adam Katz, Ann Gagné, Maxime Patenaude ainsi que Steven Plotka.

*François Allart*

# ONTARIO PODIATRIC MEDICAL ASSOCIATION

Podiatry in Ontario can rarely be said to be boring and the past year was no exception.

Once again, the OPMA engaged in negotiations with the Ministry of Health and Long-Term Care relating to an increase in the OHIP fee-for-service schedule, along with the four other professions (other than medicine) who are authorized to bill OHIP. The negotiations were sporadic and reached no conclusion. Earlier this year, the Ministry of Health threatened to de-list all health-care practitioners except MD's. In the May budget of Premier Dalton McGuinty, it was announced that podiatrists were the only profession that survived the cut. This was largely due to lobbying, not only by our small group, but by our patients.

The OPMA worked with the CPMA in order to reinstate podiatrists' right to prescribe benzodiazepines under the (federal) Controlled Drugs and Substances Act. We will continue to work with the CPMA in order to have podiatrists defined as "practitioners" for purposes of that Act. After nearly 10 years of work, delay and general frustration, the College of Chiropodists of Ontario has submitted a draft drug regulation to the government that will, once enacted, confirm podiatrists' right to use and prescribe a wide range of drugs in Ontario.

The OPMA is part of an Application under the (federal) Primary Health Care Transition Fund to establish a multi-disciplinary, primary care pilot project in Kingston, Ontario focusing on seniors. The Application survived the first round of review and is now in the second round.

The OPMA has led the charge to convince insurance companies to limit coverage of orthotics to those prescribed by podiatrists and a few other professions in order to reduce fraud and excessive or inappropriate prescriptions. More and more insurance companies are doing so.

Perhaps (and I use the term "perhaps" advisedly) the most significant event of the past year was the negotiation of an agreement between the OPMA and the Ontario Society of Chiropodists (OSC), pursuant to which both parties agreed to work together to substitute chiropody, with a CPME-accredited podiatry model of footcare in Ontario. The College of Chiropodists has promised to contribute financially to assist in the implementation of the Agreement. Never before have the three major stakeholders come together in this way. This Agreement seeks to reverse the current situation. In future, the profession would be known as "podiatry", the regulatory college would be known as the College of Podiatrists of Ontario. Current chiropodists who upgrade to the podiatric competencies would be authorized to practise as full-scope podiatrists and the remaining chiropodists would continue to practise within the chiropody scope of practice as a class of members of the podiatry profession that would eventually wither away through attrition. This will probably require the creation of a podiatry school in Ontario. For that and other reasons, this is not something that is likely to be achieved overnight.

Relations between the podiatry profession in Ontario and our regulatory body have historically been very strained. It was always podiatrists' perception that our regulatory body gave podiatry short shrift and expended considerable resources in advancing the chiropody profession. As OPMA President, I have been gratified to see relations with the College of Chiropodists improve immensely over the past year and I look forward to a continuing improvement in that working relationship.

*Millicent Vorkapich-Hill*, DPM
*President*

# MANITOBA PODIATRY ASSOCIATION REPORT

Currently there are 25 licensed practitioners in Manitoba. Twenty-four are U.K. grads and one D.Ch.

Sheree Ashton from Temple University has been in contact re a pharmacology course based on the DPM syllabus. We will meet with her in the summer to discuss further.

We are meeting with Manitoba Health to discuss a number of issues particularly a new fee schedule for welfare and other clients, prescribers for Ritchie braces and other AFO's and coverage/treatment for social service clients who are diabetic.

A.I.T. seems to be stalled. Manitoba is still strongly in favour of an educational review being completed.

The announcement of the Podiatry School in Quebec is seen as very positive in Manitoba. It is hoped that once the course is established there will be an opportunity to develop bridging courses for non-DPM's in Canada.

*Alexander (Sandy) Todd, D.Pod.M.*
*President*

# FIP LAUNCHES NEW LEARNING OPPORTUNITIES FOR MEMBERS

If there was ever an event that suggested the need to acquire a fast connection to the Internet, this is it! FIP has begun the first international series of continuing medical education (CME) or continuing professional development (CPD) programs on the Internet. "After months of discussions, negotiations and planning," according to President Dr. Ronald Lepow, "FIP now makes CME/CPD available to our membership worldwide."

Members are encouraged to visit www.fipneet.org and click Latest News: Online CPD/CME to experience the value of these educational programs. Presently two modules are available for viewing and learning: a lecture entitled calcaneo valgus Flatfoot and a Webcast presentation discussing orthotic control of the child. Both segments, like all future segments, will be offered in both English and French with clear learning objectives as well as opportunities for self-testing. Lepow noted that: "Internationally, the profession of podiatry can stand proudly together with other major health disciplines in its ability to offer its members opportunities to expand and deepen their professional knowledge. FIP's newest Website innovation provides attractive and easily understood learning experiences available to podiatrists wherever they live in the world."

"I wish to thank all who have worked so diligently and tirelessly to make this wonderful benefit for our membership become a reality. I wish to express appreciation to Dr. Richard Jay and eMedtrain who have been collaborating with FIP for over a year to make this event possible. We look forward to working with them for many, many years in the future," Lepow said.

According to Dr. Lepow, the Board of Directors of FIP will continue its work in this important area to expand program offerings at Online CME/CPD in order to strengthen the knowledge base of podiatrists worldwide.

For further information, contact Anthony J. McNevin, CAE, Director: North American Office, Fédération Internationale des Podologues at 1793 Milboro Drive, Rockville, MD USA 20854.

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# ALBERTA PODIATRY ASSOCIATION PRESIDENT'S REPORT

As one of our top priorities, the Alberta Podiatry Association continues to pursue the issue regarding the prescribing of narcotics. In addition to the efforts already made by Alberta on this issue, we also rallied around the CPMA's efforts. By working cohesively as a profession, I do believe that we are making major inroads on this issue, and certainly the correspondence between Health Canada and the Alberta Podiatry Association does indicate that changes are occurring. In fact, the October 15, 2003 publication of the Canada Gazette noted that podiatrists in Alberta, British Columbia, Ontario and Quebec have had the reinstatement of the prescribing rights for benzodiazepines. This reinstatement came about as a result of our continued lobbying, dialogues, meetings and correspondence with Health Canada and the ministers of both Alberta Health & Wellness and Health Canada. We are now actively working on the other major goal, namely the establishment of narcotic prescribing rights under the Controlled Drugs and Substances Act for podiatrists. With the tremendous support shown by both ministers, and our ongoing interaction with them, I am confident that we will soon see a resolution to this issue as well.

At the provincial level, we also received encouraging news when the Minister of Alberta Health & Wellness announced that the provincial government is not making any changes to the current situation regarding the funding of podiatric services in Alberta.

Our association also continues to be involved with a yearly conference. While it has traditionally been held in the spring in Banff, we are currently working out the details for a 2005 Region VII conference wich will be held October 28-30, 2005. This conference will also host the 2005 CPMA Annual General Meeting and the Alberta Podiatry Annual General Meeting. We encourage everyone to attend this great conference in a fabulous location! More details will be provided soon.

We are also making preparations for our amalgamation into the College of Physicians and Surgeons of Alberta, which is scheduled to take place near the end of 2004 or early 2005.

*Mario G. Turanovic D.P.M.*
*President, Alberta Podiatry Association*

# Benzodiazepines: A Brief Overview

Benzodiazepines were first introduced in the 1960's to replace barbiturates. The benzodiazepines are widely prescribed for a variety of conditions including insomnia, anxiety, muscle spasms, convulsive disorders, presurgical sedation, and also in the detoxification from alcohol and other substances. They are generally considered safer than the barbiturates as they cause less drowsiness at therapeutic doses and toxic doses are less likely to be fatal. In the daily practice of podiatric medicine they are not widely indicated, however they are very effective in quelling anxiety associated with foot surgery. Benzodiazepines are not without abuse potential and as such the following is a brief review of their mechanism of action, side effects, toxicity, and general dosing guidelines so that we may maximize our clinical outcome and minimize any potential liability.

Benzodiazepines are classified as long, intermediate, and short acting (Table 1) depending on how quickly they are metabolized.

**LONG ACTING**

Chlordiazepoxide (Librax)
Clorazepate (Tranxene)
Diazepam (Valium)
Flurazepam (Dalmane)

**INTERMEDIATE ACTING**

Alprazolam (Xanax)
Clonazepam (Klonopin)
Lorazepam (Ativan)
Temazepam (Restoril)

**SHORT ACTING**

Midazolam (Versed)
Triazolam (Halcion)

TABLE 1: *Partial list of commonly prescribed benzodiazepines.*

The exact mechanism of action of benzodiazepines is unknown, but they are all thought to act through the central nervous system to enhance the action of gamma-amino butyric acid (GABA). GABA is an inhibitory neurotransmitter in the central nervous system and as such all benzodiazepines will depress the central nervous system. Each benzodiazepine has derivatives that are site-specific thereby allowing this group of medications to be further sub-classified according to their clinical indications (Table 2).

**CONVULSIVE DISORDERS**

Diazepam (Valium)
Clonazepam (Klonopin)
Clorazepate (Tranxene)
Parenteral Lorazepam (Ativan)

**ANXIETY, TENSION, AND INSOMNIA**

Alprazolam (Xanax)
Diazepam (Valium)
Lorazepam (Ativan)
Triazolam (Halcion)

**CONSCIOUS SEDATION OR AMNESIA**

Diazepam (Valium)
Lorazepam (Ativan)
Midazolam (Versed)

**MUSCLE TREMORS or SPASMS**

Diazepam (Valium)
Chlordiazepoxide (Librax)

TABLE 2: *Clinical indications for benzodiazepines*

At therapeutic doses, benzodiazepines will cause drowsiness and impaired motor function. At toxic doses, patients will experience severe weakness, shortness of breath or difficulty breathing, bradycardia, slurred speech, vertigo, and confusion. Prolonged use of benzodiazepines will cause physical dependency and withdrawal symptoms once the drug is stopped. Patients with a previous medical history of dependency should be prescribed benzodiazepines with caution and consultation with the family physician is highly recommended.

When taking benzodiazepines, patients should be instructed not to consume alcohol or other central nervous system depressants, including antihistamines, analgesics, antidepressants, and barbiturates. Patients should also be told to avoid activities that require alertness and muscle coordination. Smoking will decrease the effectiveness of this class of medication and the patients should be counselled regarding this. When prescribed for the elderly patient lower doses are indicated, as their central nervous systems are more sensitive to the effects of benzodiazepines. Serious side effects of hypotension, apnea, bradycardia, and cardiac arrest have been reported in the geriatric patient. The same cautions apply to the pediatric patient.

Benzodiazepine overdose is treated with the benzodiazepine antagonist flumazenil (Anexate). The reversal of the sedative effects of benzodiazepines should occur within 30 seconds to 1 minute after administration of this intravenous medication. As the duration of action of flumazenil is less than benzodiazepines, the patient's level of consciousness needs to be continually monitored.

Diazepam and lorazepam are the two most commonly used benzodiazepines preoperatively in an office setting. Commonly, diazepam is administered 2 hours before surgery with the usual dose being 5 to 10 mg. Lorazepam 2 mg sublingual one hour before surgery is highly effective in the office setting. Given the patient's level of anxiety, Lorazepam 2 mg sublingual at bedtime the night before surgery and once again 1 hour before surgery is effective at relieving anxiety and invoking amnesia. Midazolam is a water-soluble benzodiazepine that is only administered intravenously. It is 3 to 4 times more potent than diazepam with a shorter duration of action.

For the podiatric surgeon, benzodiazepines are highly effective and safe when used in the perioperative period. They have no indications for use in the daily practice of podiatric medicine or for any extended period of time in a surgical patient.

*Hiedi Postowski*, D.P.M.

References: 1. Longo LP, Johnson B. Addiction: Part 1. Benzodiazepines-side effects, abuse risk, and alternatives. American Family Physician 2000.
2. Physician's Drug Handbook, 8th Edition: Springhouse 2000

# BRITISH COLUMBIA ASSOCIATION OF PODIATRISTS

The year 2003 was the second year after de-listing of Podiatric services by The Medical Services Plan of British Columbia (MSPBC). The majority of practitioners within the Province are providing services to their patients in accordance with the fee schedule as established by BCAP, although there are a few who have chosen to deviate from the standard schedule.

BCAP is still in the process of finalising a more updated and comprehensive surgical fee schedule with MSPBC. After several revisions in 2002 and 2003, we are at the stage of final drafting.

The Podiatry Act in its present form will be replaced by the government in 2004. This will be replaced by the Health Professions Act. The Board of Examiners of Podiatry have to re-write its by-laws to conform to new regulations. BCAP was formed as a result of the Podiatry Act, and will be replaced by a new association BCPMA (British Columbia Podiatric Medical Association).

An initial meeting with Blue Cross, who serves as the provider for DVA, RCMP and the Armed Forces, is scheduled for October. This is a preliminary meeting modelled after what Blue Cross has accomplished in standardising payment schedule for physiotherapy treatments across Canada for these groups.

With the assistance of Karyo, the media relations firm acting on behalf of BCAP, the official web site for BCAP: www.foothealth.ca was launched in April of 2003 to coincide with our seminar at Whistler, B.C. Phase 1 of the project covered general education information on common foot problems, with locations of Podiatric offices posted as well. Phase 2 will be completed in 2004, and will encompass a members section. BCAP members will be able to access this section via separate identification, and meeting minutes, forms for license renewal and Association news will be posted.

The Shoe Drive for 2003 was picked up by local television CTV. Dr. Stern had pictures taken with News Anchor personnel for both the 5:00 and 6:00 p.m. show. We are hoping for sponsorship with CTV for the next shoe drive in 2004.

BCAP sponsored Sports Med BC within the Sun Run for 2003. We were involved with production of three segments within the Sun Run training program. Dr's J. Stern, K. Armstrong, and D. Brooks each acted as spokesperson for their segments. The videotaped segments will be incorporated into the website. Dr. A. Boroditsky was also interviewed by Steve Darling on the morning news with BCTV.

BCAP developed a new logo and by year-end, will produce a total of three pamphlets. Topics on Podiatry, Diabetes and Orthosis are scheduled for printing this year. New topics will be added on at a later date when our budget allows. Templates on Podiatry and Orthotics for community newspaper advertising were prepared as well. This allows practitioners to easily place uniform and concise messages in their local paper.

The year 2003 had been a busy time for the Board of Examiners in Podiatry and The Executives of BCAP. There appears to be more tasks lying ahead in the upcoming year. I thank the Board and Executive members who have sacrificed their time and effort on behalf of our profession.

*Michael Y. Choi*, D.P.M.
*President* BCAP

SUPPORT THE CPEF AND HAVE A BALL!!

**TEXAS SCRAMBLE FORMAT**

Great Golf, Great Course, Great Fun, Great Prizes

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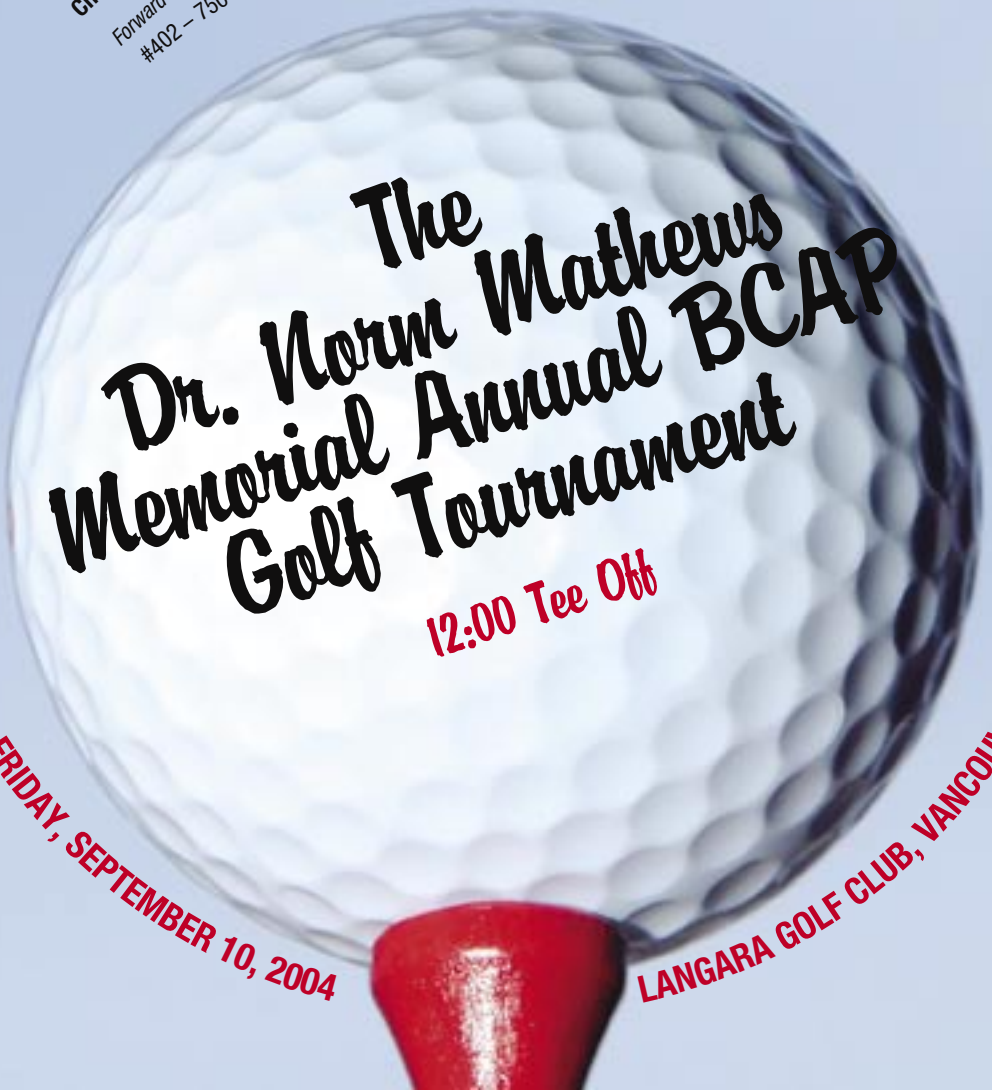

# The Dr. Norm Mathews Memorial Annual BCAP Golf Tournament

12:00 Tee Off

FRIDAY, SEPTEMBER 10, 2004

LANGARA GOLF CLUB, VANCOUVER, B.C.

# LIVE WELL WITH DIABETES

## A CONFERENCE FOR HEALTH CARE PROFESSIONALS

november 20 & 21

Coast Stanley Park Hotel
Vancouver, BC

12 CME credits applied for

Seminar fee and registration info to follow in the mail soon.

For more information, contact
Dr. Timothy Kalla
604-732-3513

The BCAP in conjunction with the Canadian Diabetes Association and CME UBC invite you to a special diabetes seminar.

A group of key diabetes opinion leaders have been assembled to present the latest trends in diabetes management and the new Canadian care guidelines. This is a unique opportunity to interact with other diabetes health care providers and to showcase podiatry as an integral part of the diabetes health care team.

## saturday, november 20

**8:00** — opening plenary — *Dr. Keith Dawson*

| | DIABETES IN GENERAL | DIABETIC VASCULAR DISEASE |
|---|---|---|
| 9:00 | Diabetes: What's New and Important for Primary Caregivers<br>*Dr. Andrew Farquhar* | Peripheral Vascular Assessment: Current Trends<br>*Dr. Lynn Doyle* |
| 9:45 | New Insulin: CDA Guideline-based therapy for Family Physicians<br>*Dr. Keith Dawson* | Hyperlipidemias in Diabetes Mellitus: When and How to Treat<br>*Dr. Greg Bondy* |

**10:30** — health break

| | | |
|---|---|---|
| 11:00 | Diabetes: The Endocrinologist's Perspective<br>*Dr. Clarissa Wallace* | Atherosclerotic Cardiovascular Disease in Diabetes: MI and CVA<br>*Dr. Ken Gin* |
| 11:45 | Glucometers: How, Why, and for Whom<br>*Dr. Marshall Dahl* | Canada on the Move: Exercise Programs for Persons With Diabetes<br>*Dr. Diane Finegood* |

**12:30** — lunch break

*"Diabetes on the Run: An Athlete's Perspective"*

| | DIABETIC NEUROPATHY | DIABETIC NEPHROPATHY |
|---|---|---|
| 13:30 | Wound Healing for Diabetics<br>*Dr. Brian T Kunimoto* | Diabetic Nephropathy: How to Prevent and Delay Progression<br>*Dr. Mohamud Karim* |
| 14:15 | Painless Oblivion: The Walking Wounded<br>*Dr. Timothy Kalla* | Dialysis: Fistulas and Shunts. What the Family Physician Needs to Know<br>*Dr. Kamyar Kazemi* |

**15:00** — health break

| | | |
|---|---|---|
| 15:30 | Current Treatments: Painful Peripheral Neuropathy<br>*Dr. Christine Chapman* | Team Management of Renal Failure: The Family Practice / Nephrologist Partnership<br>*Dr. Sabrina Gill* |
| 16:15 | The Charcot Foot: What Not to Miss<br>*Dr. Alastair Younger* | Transplant Recipients: Dealing With Rejection<br>*Dr. Paul Keown* |

**17:00** — wine & cheese reception

## sunday, november 21

| | DIABETIC RETINOPATHY | SPECIAL TOPICS |
|---|---|---|
| 9:00 | Diabetic Retinopathy<br>*Dr. Katherine Paton* | Nutrition in Diabetes Management<br>*Sharon Leung (VGH Diabetes Centre)* |
| 9:45 | Laser Therapy of Retinopathy<br>*Dr. David Maberley* | Gestational Diabetes<br>*Dr. Jason Kong* |

**10:30** — health break

| | | |
|---|---|---|
| 11:00 | Infectious Disease in Diabetes<br>*Dr. Robert Reynolds* | Diabetes for the Dermatologist<br>*Dr. Roberta Ongley* |
| 11:45 | Obesity Management: A New Approach<br>*Dr. Deborah Schwartz* | Islet Cell Transplantation: What is the Latest?<br>*Dr. David Thompson* |

**12:30** — safe journey home

# Precision Orthotics

#4-744 Fairview Road, Victoria, BC V9A 5T9

*"hand crafted quality using leading edge technology"*

**Precision Orthotics is one of Canada's premier custom orthotic laboratories. We have been dealing exclusively with Canadian podiatrists since 1988. We carry a full line of functional and accommodative orthotic devices.**

We use AOMS, the leading computer software for manufacturing the vast majority of the orthotics that we produce for our clients.

Factors that make Precision Orthotics stand out from the crowd:

- Precision Orthotics consistently manufactures exceptionally high quality orthotic devices,
- Precision Orthotics routinely accommodates special design requests by our clients,
- Precision Orthotics is very easy to deal with, and
- Precision Orthotics provides outstanding customer service.

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e-mail: info@precisionorthotics.com

# Penlac™

nail lacquer

(ciclopirox) Topical Solution, 8%

## ACTIONS AND CLINICAL PHARMACOLOGY

Ciclopirox free acid is an antimycotic agent that inhibits the growth of a number of fungi *in vitro* including *Trichophyton mentagrophytes, Trichophyton rubrum, Microsporum canis, Epidermophyton floccosum, Candida albicans, Candida tropicalis* and *Candida pseudotropicalis.*

The mechanism of action of ciclopirox has been investigated using various *in vitro* and *in vivo* infection models. One *in vitro* study suggested that ciclopirox acts by chelation of polyvalent cations ($Fe^{+3}$ or $Al^{+3}$) resulting in the inhibition of the metal-dependent enzymes that are responsible for the degradation of peroxides within the fungal cell. The clinical significance of this observation is not known.

### Pharmacokinetics

As demonstrated in pharmacokinetic studies in animals and man, ciclopirox olamine is rapidly absorbed after oral administration and completely eliminated in all species via feces and urine. Most of the compound is excreted either unchanged or as glucuronide. After oral administration of 10 mg of radiolabelled drug ($^{14}$C-ciclopirox) to healthy volunteers, approximately 96% of the radioactivity was excreted renally within 12 hours of administration. Ninety-four percent of the renally excreted radioactivity was in the form of glucuronides. Thus, glucuronidation is the main metabolic pathway of this compound.

Systemic absorption of ciclopirox was determined in 5 patients with dermatophytic onychomycoses after application of PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER, to all 20 digits and adjacent 5 mm of skin once daily for 6 months. Random serum concentrations and 24 hour urinary excretion of ciclopirox were determined at 2 weeks and at 1, 2, 4 and 6 months after initiation of treatment and 4 weeks post-treatment. In this study, ciclopirox serum-levels-ranged from 12-80 ng/mL. Based on urinary data, mean absorption of ciclopirox from the dosage form was <5% of the applied dose. One month after cessation of treatment, serum and urine levels of ciclopirox were below the limit of detection. In 2 vehicle-controlled trials, patients applied PENLAC to all toenails and affected fingernails. Out of a total of 66 randomly selected patients on active treatment, 24 had detectable serum ciclopirox concentrations at some point during the dosing interval (range 10.0-24.6 ng/mL). It should be noted that 11 of these 24 patients took concomitant medication containing ciclopirox as ciclopirox olamine (Loprox® Cream).

The penetration of PENLAC was evaluated in an *in vitro* investigation. Radiolabelled ciclopirox applied once to onychomycotic toenails that were avulsed demonstrated penetration up to a depth of approximately 0.4 mm. Nail plate concentrations decreased as a function of nail depth. The clinical significance of these findings in nail plates is unknown. Nail bed concentrations were not determined.

## INDICATIONS AND CLINICAL USE

**Please read this entire section carefully to fully understand the indication for this product.**

Topical treatment with PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER is indicated as part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis (due to *Trichophyton rubrum*) of fingernails and toenails without lunula involvement. The comprehensive management program includes frequent removal of unattached, infected nails (e.g., monthly) by a health care professional with special competence in the diagnosis and treatment of nail disorders, including minor nail procedures. PENLAC should therefore be used only under medical supervision. The safety and efficacy of daily use for longer than 48 weeks have not been established. (See **PRECAUTIONS**.)

### Pivotal Clinical Trial Data

PENLAC was used to treat onychomycosis of the great toenail (without lunula involvement) in 2 double-blind, placebo-controlled pivotal studies. Patients were treated once daily for up to 48 weeks in conjunction with monthly removal of the unattached, infected toenail by the investigator. At baseline, patients had 20-65% involvement of the target nail-plate.

**Endpoint ITT Population**

| Efficacy Variable | Study 312‡ | | Study 313‡ | |
|---|---|---|---|---|
| | Ciclopirox | Placebo | Ciclopirox | Placebo |
| Treatment Success[1] | 8/107 (8%) | 1/107 (1%) | 13/115 (11%) | 1/115 (1%) |
| Treatment Cure[2] | 6/110 (6%)† | 1/109 (1%) | 10/118 (9%) | 0/117 (0%) |
| Mycological Cure[3] | 30/105 (29%) | 14/105 (13%) | 39/113 (35%) | 10/114 (9%) |

[1] Treatment Success : *negative culture, negative KOH, ≤10% involvement target nail,* [2] Treatment Cure : *negative culture & KOH, Global Evaluation Score = Cleared,* [3] Mycological Cure : *negative culture, negative KOH,* ‡ Denominators differ across variables because of missing data, † $p$=0.055. All other values statistically significant (CMH ≤0.02, stratified by centre)

Post-treatment efficacy assessments were scheduled only for patients who achieved treatment cure. Some data on the post-treatment efficacy of the product are available for 12 patients. Twelve weeks after stopping ciclopirox treatment, 3/6 patients maintained treatment success, and 6/9 patients maintained negative mycology reports.

## CONTRAINDICATIONS

PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER is contraindicated in individuals who have shown hypersensitivity to any of its components.

## WARNINGS

PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER is not for ophthalmic, oral, or intravaginal use. For use on nails and immediately adjacent skin only.

## PRECAUTIONS

No studies have been conducted to determine whether ciclopirox might reduce the effectiveness of systemic antifungal agents for onychomycosis. Therefore, the concomitant use of PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER and systemic antifungal agents for onychomycosis, is not recommended. (See **INDICATIONS AND CLINICAL USE**.)

The effectiveness and safety in the following populations have not been studied, as the clinical trials with PENLAC excluded patients who: were pregnant or nursing, planned to become pregnant, had a history of immunosuppression (e.g., extensive, persistent, or unusual distribution of dermatomycoses, extensive seborrheic dermatitis, recent or recurring herpes zoster, or persistent herpes simplex), were HIV seropositive, received organ transplant, required medication to control epilepsy, were insulin dependent diabetics or had diabetic neuropathy. Patients with severe plantar (moccasin) tinea pedis were also excluded.

So far there is no relevant clinical experience with patients with insulin dependent diabetes or who have diabetic neuropathy. The risk of removal of the unattached, infected nail, by the health care professional and trimming by the patient should be carefully considered before prescribing to patients with a history of insulin dependent diabetes mellitus or diabetic neuropathy.

If a reaction suggesting sensitivity or chemical irritation should occur with the use of PENLAC, treatment should be discontinued and appropriate therapy instituted.

### Use in Pregnancy

Teratology studies in mice, rats, rabbits, and monkeys at oral doses of up to 77, 23, 23, or 38.5 mg, respectively, of ciclopirox as ciclopirox olamine/kg/day, or in rats and rabbits receiving topical doses of up to 92.4 and 77 mg/kg/day, respectively, did not indicate any significant fetal malformations.

Teratology studies with ciclopirox free acid were performed in rats with oral doses of 20, 50, or 125 mg/kg/day and in rabbits with oral doses of 12.5, 32, or 80 mg/kg/day; no significant fetal malformations were noted.

There are no adequate or well-controlled studies of topically applied ciclopirox in pregnant women. PENLAC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### Nursing Mothers

It is not known whether this drug is excreted in human milk. Since many drugs are excreted in human milk, caution should be exercised when PENLAC is administered to a nursing woman.

### Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

### Geriatric Use

Vehicle-controlled clinical trials of PENLAC conducted in the US did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between elderly and younger patients.

### Information To Be Provided To Patients

**Patients should be provided with instructions regarding the use of PENLAC (see INFORMATION FOR THE PATIENT).**

The patient should be told:

1. To avoid contact with the eyes and mucous membranes. Contact with skin other than skin immediately surrounding the treated nail(s) should be avoided. PENLAC is for external use only.
2. To apply PENLAC evenly over the entire nail plate and 5 mm of surrounding skin. If possible, PENLAC should be applied to the nail bed, hyponychium, and the under surface of the nail plate when it is free of the nail bed (e.g., onycholysis). Contact with the surrounding skin may produce mild, transient irritation (redness).
3. To file and trim nails on a weekly basis during treatment with PENLAC.
4. That removal of the unattached, infected nail, as frequently as monthly, by a health care professional is needed with use of this medication.
5. To inform a health care professional if they have diabetes or problems with numbness in the toes or fingers for consideration of the appropriate nail management program.
6. To inform a health care professional if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, oozing).
7. That up to 48 weeks of daily application with PENLAC and professional removal of the unattached, infected nail, as frequently as monthly, are considered the full treatment needed to achieve a clear or almost clear nail (defined as 10% or less residual nail involvement).
8. That 6 months of therapy with professional removal of the unattached, infected nail may be required before initial improvement of symptoms is noticed.
9. That a completely clear nail may not be achieved with use of this medication. In clinical studies less than 12% of patients were able to achieve either a completely clear or almost clear toenail.
10. That he/she should not use nail polish or other nail cosmetic products on the treated nails.
11. To not use the medication for any disorder other than that for which it is prescribed.
12. To avoid use near heat or open flame, because product is flammable.

## ADVERSE REACTIONS

In the vehicle-controlled clinical trials conducted in the US, 9% (30/327) of patients treated with PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER and 7% (23/328) of patients treated with vehicle reported treatment-emergent adverse events (TEAE) considered by the investigator to be causally related to the test material. With the exception of Skin and Appendages, the incidence of these adverse events, within each body system, was similar between the treatment groups and was less than 1%. For Skin and Appendages, 8% (27/327) and 4% (14/328) of patients in the ciclopirox and vehicle groups, respectively, reported at least 1 adverse event.

Periungual erythema and erythema of the proximal nail fold were the most common TEAEs causally related to study drug. These events (coded as "rash") were reported in 5% (16/327) of patients treated with PENLAC and 1% (3/328) of patients treated with vehicle.

Other TEAEs thought to be causally related to study material in the US vehicle-controlled studies included nail disorders such as shape change, irritation, ingrown toenail, and discoloration. The incidence of nail disorders was similar between the treatment groups (2% [6/327] in the PENLAC group and 2% [7/328] in the vehicle group).

Application site reactions and/or burning sensation of the skin were considered causally related to study drug in 1% of both PENLAC- and vehicle-treated patients (3/327 and 4/328, respectively).

The following table summarizes the most common TEAEs considered causally related to study drug, as reported in the US Phase II/III vehicle-controlled trials.

| *Body System TEAE* | *PENLAC n (%)* | *Vehicle n (%)* |
|---|---|---|
| No. of Patients Treated | 327 (100.00) | 328 (100.0) |
| Patients with Related TEAEs | 30 (9.2) | 23 (7.0) |
| Skin and Appendages | 27 (8.3) | 14 (4.3) |
| Periungual erythema / erythema of proximal nail fold | 16 (4.9) | 3 (0.9) |
| Nail Disorders† | 6 (1.8) | 7 (2.1) |
| Application Site Reaction / Burning Sensation | 3 (0.9) | 4 (1.2) |
| Other‡ | 2 (0.6) | 0 (0.0) |
| All other Body Systems | 0 - 1 (0.0 - 0.3) | 0 - 3 (0 - 0.9) |

† Nail disorders such as shape change, irritation, ingrown toenail and discolouration, ‡ Other: Dry skin, pruritis

Use of PENLAC for 48 additional weeks was evaluated in an open-label extension study conducted in patients previously treated in the vehicle-controlled studies. Three percent (9/281) of patients treated with PENLAC experienced at least 1 TEAE that the investigator thought was causally related to the test material. Mild rash in the form of periungual erythema (1% [2/281]) and nail disorders (1% [4/281]) were the most frequently reported. The remainder of TEAEs considered causally related to study drug occurred at an incidence of <1%.

In controlled and open-label clinical trials conducted with ciclopirox nail lacquer, 8% outside of the US, adverse events reported were consistent with those seen in the US studies.

### Post-Marketing Experience

Contact dermatitis has been reported as an adverse reaction in post-marketing surveillance of ciclopirox-containing products, including ciclopirox nail lacquer, 8%.

## SYMPTOMS AND TREATMENT OF OVERDOSAGE

The likelihood of overdosage from topical administration of ciclopirox nail lacquer, 8% is extremely low.

In a test of acute oral toxicity in the rat, the $LD_{50}$ was greater than 10 mL/kg of ciclopirox nail lacquer, 8%. This would be equivalent to 600 mL for an adult person weighing 60 kg or more than 1000 vials of 3 mL. Furthermore, overdosage by oral ingestion of nail lacquer would be unlikely because of its unpalatable taste.

## DOSAGE AND ADMINISTRATION

PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER should be used as a component of a comprehensive management program for onychomycosis. Removal of the unattached, infected nail – as frequently as monthly – by a health care professional, weekly trimming by the patient, and daily application of the medication are all integral parts of this therapy. Careful consideration of the appropriate nail management program should be given to patients with diabetes. (See **PRECAUTIONS**.)

### Nail Care By Health Care Professionals

Removal of the unattached, infected nail – as frequently as monthly – trimming of onycholytic nail, and filing of excess horny material should be performed by professionals trained in the treatment of nail disorders.

### Nail Care By Patient

Patients should file away (with emery board) loose nail material and trim nails, as required, or as directed by the health care professional, every 7 days after PENLAC is removed with isopropyl alcohol.

PENLAC should be applied once daily (preferably at bedtime or 8 hours before washing) to all affected nails with the applicator brush provided.

PENLAC should be applied evenly over the entire nail plate.

If possible, PENLAC should be applied to the nail bed, hyponychium, and the under surface of the nail plate when it is free of the nail bed (e.g., onycholysis).

PENLAC should not be removed on a daily basis. Daily applications should be made over the previous coat and removed with isopropyl alcohol every 7 days. This cycle should be repeated throughout the duration of therapy.

## PHARMACEUTICAL INFORMATION

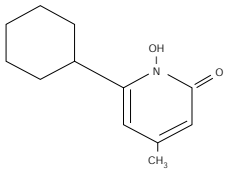
### Drug Substance

**Common Name:** Ciclopirox

**Chemical Name:** 6-cyclohexyl-1-hydroxy-4-methyl-2(1H)-pyridone

**Molecular Formula:** $C_{12}H_{17}NO_2$

**Structural Formula:**




**Molecular Weight:** 207.27

**pH:** 5.0

**pKa:** 7.2

**Description:** Ciclopirox is a white to slightly yellowish white, crystalline powder, with a melting point of 140° - 145°C. It is slightly soluble in water, very soluble in chloroform; freely soluble in dichloromethane and 96% ethanol; soluble in ether.

### Composition

Each gram of PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER contains 80 mg ciclopirox in a solution base consisting of ethyl acetate, isopropyl alcohol, and butyl monoester of poly[methylvinyl ether/maleic acid] in isopropyl alcohol. Ethyl acetate and isopropyl alcohol are solvents that vaporize after application.

### Stability and Storage Recommendations

PENLAC should be stored at room temperature between 15° and 30°C. To protect from light, replace the bottle into the carton after each use. CAUTION: Flammable. Keep away from heat and flame.

## AVAILABILITY OF DOSAGE FORMS

PENLAC (Ciclopirox Topical Solution, 8% w/w) NAIL LACQUER is a clear, colourless to slightly yellowish solution for topical application to fingernails, toenails and immediately adjacent skin only. It is available in 3 gram and 6 gram glass bottles with screw caps which are fitted with brushes.

The complete Product Monograph is available on request from Dermik Laboratories Canada Inc.

**Dermik Laboratories Canada Inc.**
2150 St. Elzear Blvd. West
Laval, Québec H7L 4A8

# DATES TO REMEMBER

**INTERNATIONAL REGION VII SCIENTIFIC SEMINAR**
October 22 - 24, 2004
Sun Valley, Idaho
For more information contact: Dr. Susan Scanlan
1-866-343-6999 or nwpodiatry@aol.com

**LIVING WELL WITH DIABETES: A CONFERENCE FOR HEALTH CARE PROFESSIONALS**
November 19 - 21, 2004
Vancouver, BC
For more information contact: Dr. Timothy Kalla
604-732-3513 or tpk@telus.net

**UNIVERSITY OF BRITISH COLUMBIA & BC ASSOCIATION OF PODIATRISTS**
**FOOT & ANKLE / PODIATRY SEMINAR**
April 8 - 10, 2005
Vancouver, BC
For more information contact: Patricia Evans
604-602-0400 or bcap@telus.net

**INTERNATIONAL REGION VII SCIENTIFIC SEMINAR**
October 28 - 30, 2005
Lake Louise, Alberta
For more information contact: Dr. Susan Scanlan
1-866-343-6999 or nwpodiatry@aol.com

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