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# The Growth of a Family

*A family-oriented approach to pregnancy care*

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**SUMMARY**

**Caring for a family during pregnancy and birth is an ideal opportunity for family physicians to assess family functioning and help the family adjust to the birth of a new child. Stress and support systems can influence the course of pregnancy, including obstetric and perinatal outcomes. A family-centered approach can help patients during this critical stage of family development.**

**RÉSUMÉ**

**Les soins à la famille pendant la grossesse et au moment de la naissance constituent pour les médecins de famille une occasion unique d'évaluer le fonctionnement de la famille et d'aider celle-ci à s'adapter à la naissance d'un nouvel enfant. Le stress et les réseaux de soutien peuvent influencer la grossesse et les résultats des soins obstétricaux et périnataux. Une approche axée sur la famille peut aider les patients à franchir ce stade critique du développement familial.**

*Can Fam Physician* 1991;37:1905-1912.

**P**ARTICIPATING WITH A FAMILY in the planning and birth of a baby is one of the most rewarding experiences in family medicine. Physicians can have an effect on patients and their families during this critical stage of family development.

The frequent prenatal visits over a few months offer a unique opportunity to observe the family's strengths and coping abilities. Over this time a relationship of trust and understanding is built. Family-centered care is valuable, because lifestyle and family health issues are critical to the pregnancy and care of the newborn. Stress, support systems, and family interaction can influence the course of pregnancy, including obstetric and perinatal outcomes.

Traditional prenatal care has been based on a medical model. The physician screens for such complications as pregnancy-induced hypertension and intrauterine growth retardation but rarely addresses the health of the family unit and other health promotion issues.

This article outlines a different approach to prenatal, delivery, and postpartum care. We offer specific suggestions for implementing a family-oriented approach throughout each stage of pregnancy, childbirth, and the .....

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newborn period. The basic goal of family-oriented pregnancy care is not only to deliver a healthy baby, but also to help parents make the adjustments needed to provide the best care for their new child.

**DEVELOPMENTAL ISSUES IN PREGNANCY AND CHILDBIRTH**

Birth is a critical stage for the young family to weather, as the marital system makes space for a new family member and the nuclear family realigns relationships with the extended family.<sup>1</sup> "The couple must make room in their relationship for the new infant, while maintaining the intimacy and sexuality of their marriage."<sup>2</sup> Becoming parents encourages couples to reflect on and alter their relationships with their own parents.

A woman's relationship with her husband strongly influences her experience of pregnancy. Gladieux<sup>3</sup> reported that women's satisfaction with pregnancy was associated with affection, discussion, and mutual inclusion within their marriages. Grossman<sup>3</sup> showed that women who were more satisfied with their marriages reported fewer symptoms during pregnancy and were better adapted at childbirth and at 1 year after delivery. These women also noted less anxiety and depression late in pregnancy and at 2 months and 1 year after delivery. Studies have shown that satisfaction with (not just the presence of) an

Table 1. WHAT ARE SOME DANGER SIGNALS?

FATHER
Never attends prenatal visit (despite flexible scheduling)
Never attends prenatal classes
Does not attend ultrasound examination
Does not attend delivery
MOTHER
Has significant ambivalent or negative feelings toward pregnancy after 20 weeks' gestation
<ul style="list-style-type: none"> <li>• Has no questions about labor and delivery</li> <li>• Denies awareness of fetal movement</li> <li>• Reports persistent feelings of wanting to run away or get it over with, especially before the last month of pregnancy</li> <li>• Sees pregnancy as interfering greatly with lifestyle or self-image</li> </ul>
Has insecure or negative feelings about her own mothering skills
<ul style="list-style-type: none"> <li>• Has no history of positive parenting role model</li> <li>• Has a history of abuse</li> <li>• Is very critical of her own abilities</li> </ul>
Has inappropriate positive feelings about pregnancy or mothering
<ul style="list-style-type: none"> <li>• Makes no plans for infant</li> <li>• Anticipates infant as friend</li> <li>• Has unrealistic expectations of newborn</li> </ul>
Has inadequate nuclear family support: marital stress, abuse
Has inadequate extended support system
<ul style="list-style-type: none"> <li>• Has no friends to help out in an emergency</li> <li>• Family offers criticism</li> <li>• Grandparents take over parenting of infant</li> </ul>
Has current or history of significant psychiatric problems
<ul style="list-style-type: none"> <li>• Has depression, suicidal ideation, schizophrenia</li> </ul>
<i>Data from McKay and Phillips.<sup>5</sup></i>

intimate relationship was significantly related to positive maternal attitudes; it was, in fact, the most important predictor.<sup>3</sup> Soule<sup>3</sup> found that the quality of a man's marital relationship before the birth is associated with his approach to fathering.

Studies have shown an increased incidence of depression and decreased marital satisfaction after the birth of the first child.<sup>4</sup> There are many stresses facing new parents. Mothers, in particular, often suffer from "role realignment." They can be confused by the role expectations of contemporary society, which often conflict with internalized culture- and family-transmitted expectations.<sup>1</sup> These stresses can result in feelings of inadequacy, anger, and frustration and can be manifested in both parents as emotional and physical distancing and inability to cope.

Men who lack confidence and have poor nurturing skills tend to be more ambivalent about the added responsibility of a child.<sup>1</sup> They have trouble committing themselves to the role of father. Temporary emotional regression and childish behavior can occur while they resolve their ambivalence over their new role.

### **OPPORTUNITIES FOR FAMILY INVOLVEMENT DURING PREGNANCY CARE**

#### **Preconception**

The preconception visit is an excellent opportunity to involve the couple in the family-oriented approach to pregnancy care. Both members of the couple need to be present to determine any genetic or familial disorders, such as Tay-Sachs disease or thalassemia, which should be diagnosed before pregnancy.

Having the couple together in your office gives you a chance to discuss a number of other issues. How does each partner feel about having a child? Is one member reluctant? The attitudes of the extended family toward children can be discussed and potential areas of conflict uncovered. In this visit, the physician has a chance to briefly assess the couple's stage in the family life cycle and how they have negotiated the tasks of previous phases. This is an opportunity to uncover possible areas of conflict or risk and to begin discussion.

### **First prenatal visit**

Family involvement is easily justified medically at this stage, to detect genetic, familial, and medical risk. The physician can also use the early prenatal visits to get acquainted with the couple and to learn about their extended families and the parenting models to which they are accustomed. Often, the father will be sitting in the waiting room and will appreciate an invitation to join you. A genogram and family Apgar<sup>5</sup> can be completed in the early prenatal period.

### **Assessing the quality of relationships.**

The quality of parent-child relations and marital relations in the family of origin help to predict the marital functioning of parents of young children.<sup>6</sup> A poor marital history together with a poor childrearing history in the family of origin make couples most susceptible to increasing differences in the way they view their marriage after the birth of a baby.<sup>6</sup> Discrepancy between husband and wife in the quality of marital relationship and parenting in the family of origin is often the best predictor of stress in a relationship.<sup>6</sup> A mother from a deprived background often has a very difficult time in pregnancy unless her increasing dependency needs are met by both her family and the health care team. If there are other children in the family, the family physician will already have knowledge of the couple's parenting skills and the quality of the parent-child relationship. Existing problems can be worked on during the pregnancy in an effort to prevent recurring dysfunctional behavior patterns. In well-functioning families, parenting techniques can be reinforced, in anticipation of expected challenges with a new baby.

Couple visits allow the family physician to explore the couple's current relationships with their families of origin and learn something about their own childhood. This information can help identify a high-risk situation (*Table 1*<sup>5</sup>). Raising issues in the interviews can stimulate the couple to have discussions at home about parenting, work changes, and their marital relationship. Unhealthy patterns of interaction are often passed from generation to generation; early intervention can help the couple and physician prevent family dysfunction.

**Involving the father.** There are many opportunities to involve the father, including prenatal visits, ultrasound examination, prenatal classes, labor and delivery, postpartum hospital visits, and well baby visits. It is vital that he be actively included right from the start.

A father's perceptions of his role are influenced by what society considers that role to be, what he has learned as a child, and what family members expect of him. Health professionals are beginning to accept the idea that his partner's pregnancy is an important event and, indeed, potentially a crisis in a prospective father's life.

Many fathers want psychosocial support from their family physicians during this period.<sup>7</sup> Williamson and English<sup>8</sup> found that family physicians knew more about stresses and sources of emotional support for women than for their husbands. Fathers in the study rated their physicians highly as a source of support, and the authors reported that including the father in the prenatal visits took no extra time.

May<sup>7</sup> describes three emotional phases through which men pass during pregnancy: announcement, moratorium, and focusing.

*Announcement:* In the announcement period the pregnancy is suspected and then confirmed. It varies in length from a few hours to a few weeks. It is characterized by great joy and excitement if the pregnancy is desired, and pain and shock if it is not.

*Moratorium:* In the moratorium phase many men put aside conscious thought about the coming baby for a time. Length varies from days to several months. The main characteristic is emotional distance, which could allow the man to work through the ambivalence he feels about the baby. Partly because they lack social supports for the emotional impact of impending fatherhood, many men take a long time to pass through this phase. Because the woman is very emotionally involved in the pregnancy at this time, marital tension and disrupted communication patterns are frequent.

During this stage, men cannot see much evidence of pregnancy. Quickening is an important event for men. Listening to the fetal heart at antenatal visits or attending the ultrasound examination can make the pregnancy more real to fathers and help develop bonding.

*Focusing:* In the focusing period, from the 25th week to the onset of labor, the father increases his involvement with the pregnancy.

The family physician should recognize and legitimize the father's reactions during these phases. Physicians are also in an excellent position to alleviate many concerns of expectant fathers, particularly concerning the health of their wives and babies.

The father should be routinely invited to all prenatal visits. Attendance at two visits during the pregnancy is essential: early on to deal with medical history and early pregnancy issues, and toward the end to discuss labor, delivery, and the postpartum period. Fathers are usually very eager to participate in prenatal care, but occasionally a woman will state that her partner is reluctant or unwilling to attend. Confusion about their role in prenatal care or rigid work schedules can prevent fathers from coming in. Physicians need to extend clear invitations to fathers and to be flexible in scheduling appointments.

A father's lack of attendance can indicate low involvement in parenting or marital distress. In these cases, it is particularly important to get the father in as early as possible and to assess the marital relationship and its effect on the pregnancy.

Once the couple is in the office, it is important to establish rapport with the father at the beginning of the visit and to acknowledge his importance throughout the pregnancy. The family physician might suggest that the father have a physical checkup. It has been reported that 20% to 40% of fathers suffer from *couvade syndrome*, which mimics symptoms of pregnancy.<sup>2</sup> The examination gives the physician an opportunity to evaluate physical and psychological symptoms and to establish a relationship with the father. This visit also acknowledges that his health is important.<sup>2</sup>

### **Second trimester**

"The second trimester is often a period of calm and increased closeness between the couple."<sup>2</sup> This is usually a time when the couple is enjoying pregnancy and the anticipation of a baby.

**Education.** These visits are an opportunity for the family physician to educate the

family regarding a number of issues: maternal and child health maintenance, normal family development, and the role of the family doctor.

*Maternal and child health maintenance:* Prenatal visits should be seen as an opportunity for health education. Because parents often are willing to make changes for the good of the baby, this is a good time to talk about smoking, alcohol, child development, accident prevention, and prevention of child abuse. The father needs to be involved in this educational process. Having both partners present can improve retention of and compliance with the doctor's advice.<sup>9</sup>

*Normal family development:* Physicians need to educate couples about the normal stresses that accompany transition to parenthood. The couple must clarify and negotiate expectations, tasks, and attitudes. Couples should be encouraged to maintain close intimate relationships, independent of their roles as parents. The physician often is able to make an early identification of families in trouble.

*The role of the family doctor:* As family physicians, we need to emphasize our interest in continuity of care, the "whole family," family development, and the psychosocial aspects of health. The physician should be seen as caregiver for all members of the family.

We need to be explicit about our perspective on family systems. Patients do not expect physicians to be concerned about stress and emotional support. Williamson and English<sup>8</sup> found that fathers were unclear about their physician's interest in anything other than biomedical, pregnancy-related issues. When the doctor expressed interest in anticipated role shifts, financial concerns, support needs, and physical health of the husband, relevant discussion and education for the couple ensued. Williamson and English<sup>8</sup> comment that this discussion did not extend the time of the prenatal visit. Furthermore, these conversations expanded the family's expectations of the physician for future care and taught them the appropriateness of the family physician's role in the care of the family as a unit.

**Life stresses and social support.** Pregnancy is often a time of increased stress. It

is not the time to move, renovate the house, or change jobs – if there is a choice! Questioning about life stress and support systems should be part of every prenatal visit.

*Obstetric difficulty:* In 1986, Istvan<sup>10</sup> published a critical review of the evidence regarding stress, anxiety, and birth outcomes. Meta-analysis of 23 studies using global obstetric difficulty as an outcome measure found that stress or anxiety about a life change was related to poor obstetric outcome in 14 of the studies.

Norbeck and Tilden<sup>11</sup> looked at life event stress and obstetric complications. Life change before pregnancy was related to pregnancy complications. A composite “emotional disequilibrium” score including depression, anxiety, and self-esteem measures was related to infant complications. Subjects in the group with several life changes and little tangible support (material resources) had the highest rate of pregnancy and infant complications. Low scores on life change and little tangible support were related to higher rates of labor and delivery complications.

There is some evidence of a relationship between life change and anxiety and premature delivery.<sup>10</sup> Berkowitz<sup>10</sup> showed that mothers who delivered before term experienced more major life events during the first and second trimesters than full-term mothers. Newton<sup>10</sup> showed that experience of a major life event was associated with both prematurity and low birth weight.

Unfortunately, the influence of maternal cigarette smoking, alcohol use, and caffeine consumption in mediating this relationship was not examined in Berkowitz’s study. A previous study had shown that cigarette smoking and alcohol use were higher in women who delivered before term.<sup>10</sup> In Newton’s study, the relationship did not remain significant after controlling for smoking. These findings are nevertheless suggestive, and the possibility that experiencing a major life event contributed to poor neonatal status either directly or mediated through increased frequency of behavior putting health at risk must be considered.

*Social support:* Social networks and social support play an important role in health, as well as in individual decision making and behavior. Normative expectations of signif-

icant others are important determinants of behavior.<sup>12</sup> Social support is a strong predictor of satisfaction with the parent role and infant care.<sup>12</sup> Social support can also have a positive effect on health by moderating the effect of stress and by facilitating coping.<sup>12</sup> Investigators have found that the effects of social support are linked more to *perceptions* of support than to the actual behavior of others.<sup>12</sup> Pregnancy can be seen as a maturational crisis – a time when additional support is necessary for successful crisis resolution.<sup>12</sup>

The classic study in this area is one by Nuckolls and colleagues.<sup>13</sup> They found that, in the presence of high life stress before and during pregnancy, psychosocial assets, including social support, were associated with fewer complications. In their sample, 91% of the women with high stress levels and few psychosocial assets had complications, compared with 33% of the women who, although they had similar high levels of stress, also had many psychosocial assets. In the absence of significant life changes, the level of psychosocial assets had no effect on pregnancy complications. The authors concluded that psychosocial assets perform a protective role during pregnancy and that social support modifies potentially pathologic effects of high stress.

*What physicians can do:* These studies have many implications for intervention. By strengthening the psychosocial assets through intervention, such as counseling and education, we might reduce the incidence of complications. The family might also respond to the physician’s encouragement to limit some life changes during pregnancy. Williamson and English<sup>8</sup> have demonstrated that stress decreases when doctors provide information, discussion, and reassurance. The health benefits of social support during pregnancy are generally attributed to its role in mediating or buffering stress. Social support can also indirectly affect health by enhancing adherence to healthy practices.

*After the birth:* Social support is an important variable for breast-feeding success. Among Anglo-American mothers, the male partner has been shown to be the single most important source of support in promoting breast-feeding.<sup>14</sup> Support from a best friend was next most important.

Among black Americans, only the best friend was predictive of breast-feeding. The woman's mother was the primary source of social support for breast-feeding among Mexican-American families. It is important to determine who has this kind of influence in a particular family.

Ramsey and associates<sup>15</sup> studied family support in a prospective pilot study of 102 mother-infant pairs. This study showed that infants of mothers who perceived their families as disengaged or enmeshed weighed less than those from moderately cohesive families. A further prospective cohort study of 833 mother-infant pairs<sup>16</sup> showed that infants of mothers who perceived their families as dysfunctional weighed on the average 126 g less than infants born to women from functional families, after adjusting for other known determinants. Women who lived alone were also found to have an increased risk of a smaller baby. Living with the extended family was better, and living with a husband was best.<sup>15</sup>

The mechanism by which family dysfunction affects birth weight is unknown. One could hypothesize that the family affects nutrition or attendance at prenatal visits. A dysfunctional family can act as a stress producer, not absorber. Stress can lower salivary IgA levels. Does it lower cervical secretory IgA? Does stress compromise the immune state, allowing for maternal intrauterine infections?

### **Third trimester**

The third trimester is usually a time of anticipation and anxiety concerning labor and delivery and the new baby. "Acknowledging and normalizing the impatience and anxiety during this period can be very helpful for couples."<sup>22</sup>

Prenatal visits during the second and third trimester are an opportunity to involve the other children in the family in the pregnancy. A child can listen to the fetal heart beat, feel the baby move, and talk about the new baby. These visits also provide an unthreatening situation in which the child can become comfortable with physical examination and with you as the family doctor. Involving siblings can help with the bonding process, decrease jealousy, and alleviate their fears about what might happen to their mother in hospital.

At visits in the third trimester, it is helpful to review the usual events of labor and delivery with the couple. Options for pain management, labor positions, breast-feeding, and circumcision should be discussed. Third trimester visits are also a good time to plan help and support for the mother and new baby after discharge from hospital, including early discharge planning or visits from the public health nurse.

### **Labor and delivery**

There are many ways to involve the family during labor and delivery. The labor nurse, father, and other family members should negotiate their roles in supporting the laboring woman. Long labor can be exhausting for both members of the couple, so having additional family members at the labor can provide more support for the mother. The father's role should depend upon the needs and desires of the woman. Some fathers ask to cut the umbilical cord or to touch the baby's head as it is delivering. Many mothers appreciate immediate skin-to-skin contact with their newborn and nursing as soon as desired.

As physicians, we need to critically look at all the procedures and interventions during labor and delivery that do not facilitate early bonding and good family functioning. This topic is beyond the scope of this article, but a critical review of interventions in obstetrics can be found in *Effective Care in Pregnancy and Childbirth*.<sup>17</sup>

### **After delivery**

Postpartum hospital visits to the mother and baby are an opportunity to both assess and involve the family. Often the grandparents will be present at the time of a visit. While meeting them, the family physician can get a feel for a number of issues, including:

- how supportive they are of their children's parenting abilities;
- their attitudes toward breast-feeding, parenting, etc;
- conflicts between family members; and
- availability of family support (babysitting, cooking, etc) for the new mother.

At the time of discharge, a meeting with both parents can address concerns. Conducting the discharge physical examination

of the newborn at the bedside allows the physician to explain normal and abnormal findings. It is also an opportunity to express confidence in the couple's competence as parents. Postpartum and newborn instructions are reviewed, and the father's participation in the care of the child can be discussed. Involving the father early on in care of both his baby and his wife may encourage him to establish bonds and show continuing interest.

### Postpartum adjustment

The most critical areas of disagreement for most couples are the use of time alone and as a couple, and the division of labor.<sup>1</sup> These conflicts need to be anticipated by the family doctor and discussed at the 6-week postpartum visit. Sexual activity should also be discussed with the couple together at this visit. Women will often experience a decreased interest in sex, possibly related to hormonal shifts, mood changes, fatigue, and pain.

Counseling is indicated when there is reason to believe that a woman is particularly vulnerable to postpartum depression. Vulnerability factors include a history of depression, especially postpartum depression, a history of depression in first-degree relatives, and high levels of stressful life events during pregnancy and after delivery.<sup>18</sup> The new father can also experience emotional and physical discomfort, such as increased fatigue, irritability, headache, difficulty concentrating, insomnia, nervousness, and restlessness.<sup>1</sup>

The physician's role is to assess the couple's coping abilities, highlight their strengths, and give them anticipatory guidance on some of the emotional changes and reorganization that a baby brings. Knowing the family's adaptability and the family and community resources at their disposal will help the physician identify families that are at risk of a dysfunctional transition to parenthood.

### CONCLUSION

One physician summed up the importance of pregnancy and delivery to the family when he said:

*The family begins with the relationship between a man and a woman, but it is really not a family unit until a child is born. Therefore the events immedi-*

*ately preceding and surrounding the birth of a child have great social importance for family development.<sup>2</sup>*

The transition to parenthood is a time to prevent family dysfunction and the perpetuation of unhealthy patterns from past generations. The family physician who is in tune with the major changes going on in a family during this critical period can play an important part in building family strengths. A family-oriented approach that cares for the social, emotional, and biological needs of the entire family during pregnancy and birth sets the stage for promoting a healthy family throughout the life cycle. ■

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# Nizoral

ketoconazole cream 2%

## TOPICAL ANTIFUNGAL AGENT

**ACTION:** *In vitro* studies suggest that the antifungal properties of NIZORAL (ketoconazole) may be related to its ability to impair the synthesis of ergosterol, a component of fungal and yeast cell membranes. Without the availability of this essential sterol, there are morphological alterations of the fungal and yeast cell membranes manifested as abnormal membranous inclusions between the cell wall and the plasma membrane. The inhibition of ergosterol synthesis has been attributed to interference with the reactions involved in the removal of the 14- $\alpha$ -methyl group of the precursor of ergosterol, lanosterol.

**INDICATIONS:** NIZORAL cream 2% may be indicated for the topical treatment of tinea pedis, tinea corporis and tinea cruris caused by *Trichophyton rubrum*, *T. mentagrophytes* and *Epidermophyton floccosum*; and in the treatment of tinea versicolor (pityriasis) caused by *Malassezia furfur* (*Pityrosporum orbiculare*); and in the treatment of seborrheic dermatitis caused by *Pityrosporum ovale*; and in the treatment of cutaneous candidiasis caused by *Candida albicans*.

**CONTRAINDICATIONS:** NIZORAL cream 2% is contraindicated in persons who have shown hypersensitivity to the active or excipient ingredients of this formulation.

**WARNINGS:** NIZORAL cream 2% should never be employed for the treatment of infections of the eye.

**PRECAUTIONS:** If a reaction suggesting sensitivity or chemical irritation should occur, use of NIZORAL cream 2% should be promptly discontinued.

Limited short term studies in animals and in human volunteers on whom limited quantities of NIZORAL cream 2% were tested have failed to demonstrate absorption of ketoconazole in detectable amounts. Due to the teratogenic nature of the active ingredient, ketoconazole, caution should be exercised when NIZORAL cream 2% is administered to pregnant or nursing women.

Cross sensitivity with miconazole and other imidazoles may exist and caution is suggested when NIZORAL cream 2% is employed in patients with known sensitivities to imidazoles.

**ADVERSE REACTIONS:** Short-term studies indicate that NIZORAL cream 2% is well tolerated by the skin. During clinical trials, 43 (5.0%) of 867 patients treated with the cream and 3 (1.8%) of 167 patients treated with placebo reported side effects consisting mainly of severe irritation, pruritus and stinging. One of the patients treated with NIZORAL cream 2% developed a painful allergic reaction (swelling of the foot).

**SYMPTOMS AND TREATMENT OF OVERDOSAGE:** There has been no experience with overdosage of NIZORAL cream 2%. Treatment should include general supportive measures.

**DOSAGE AND ADMINISTRATION:** When clinically warranted, therapy with NIZORAL cream 2% may be initiated while results of culture and susceptibility tests are pending. Treatment should be adjusted according to the findings.

NIZORAL cream 2% should be applied to the affected and immediate surrounding area in patients with the following conditions:

CONDITIONS	FREQUENCY	DURATION
Tinea pedis	once daily	4-6 weeks
Tinea corporis	once daily	3-4 weeks
Tinea cruris	once daily	2-4 weeks
Tinea versicolor	once daily	2-3 weeks
Cutaneous candidiasis	once daily	2-3 weeks
More resistant cases may be treated twice daily depending on patient response.		
Seborrheic dermatitis	twice daily	4 weeks

The full course of therapy should be followed to reduce the possibility of recurrence. If however, there is no response within the recommended treatment period, the diagnosis should be re-evaluated.

The safety of NIZORAL cream 2% has not been established with treatment periods exceeding those recommended, therefore, treatment must not exceed the recommended duration of therapy indicated above.

**DOSAGE FORM:** NIZORAL cream 2% is a white odourless cream containing 20 mg ketoconazole per gram and is supplied in 30 g tubes. Full Product Monograph available on request.

**REFERENCES:** 1. Stoppie P et al.: An Autoradiographic Study of the Penetration of a 2% Ketoconazole Cream Formulation into Human Skin. Data on file at Janssen Pharmaceutica Inc. 2. Nizoral cream product monograph. 3. Swanson NA.: Double-blind Randomized Comparative Trial of Once- and Twice-Daily Ketoconazole 2% Cream and Placebo in the Treatment of Tinea Pedis. Data on file at Janssen Pharmaceutica Inc. 4. Cauwenbergh G.: Ketoconazole 2% Cream for the Treatment of Dermatofungal Infections in Patients who Failed in Previous Antifungal Therapy. Data on file at Janssen Pharmaceutica Inc. 5. Savin RC, Horowitz SN.: Double-Blind Comparison of Ketoconazole 2% Cream and Placebo in the Treatment of Tinea Versicolor. *J Am Acad Dermatol* 1986; 15:500-503. 6. Taplin D.: Double-Blind Comparison of 2% Ketoconazole Cream and Placebo in the Treatment of Tinea Corporis and Tinea Cruris. Data on file at Janssen Pharmaceutica Inc.



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that helps treat a serious drug addiction.

# NICORETTE

**Nicotine resin complex.  
Anti-smoking aid.**

## Prescribing Information

### INDICATION:

Nicorette Chewing Gum is designed to provide partial substitution for the nicotine in cigarette smoke and is intended as a temporary aid in cushioning the patient against the psychopharmacological trauma of withdrawal.

### CONTRAINDICATIONS:

Nicotine is contraindicated in pregnancy because of its known adverse effects on the fetus. Nicorette is also contraindicated in breast feeding mothers, as nicotine is excreted in breast milk. Nicorette is contraindicated in non-smokers and in children.

### PRECAUTIONS:

Nicorette may cause an exacerbation of symptoms in patients suffering from inflammation or disease of the oral cavity, gastritis, or peptic ulceration. Nicorette should be prescribed with care in patients with angina, coronary artery disease or peripheral vascular disease.

Excessive weight gain is sometimes associated with abstinence from smoking. The mechanism for this is believed to be the abstinence from the oral habit of cigarette smoking and its replacement by increased intake of food. For this reason a patient on Nicorette should be weighed at regular intervals with modifications in diet as necessary.

Nicorette should be chewed slowly. Vigorous chewing can enhance adverse reactions and should therefore be avoided.

### ADVERSE REACTIONS:

Nicorette can sometimes cause, in the early days of treatment, canker sores, throat irritation, excessive salivation and hiccups. However, these symptoms are usually more frequent and severe with the 4 mg than the 2 mg preparation. Nausea, vomiting, belching, flatulence, and aggravation of dyspepsia have been reported. Allergic skin reactions have been reported on rare occasions. Nicorette may stick to full or partial dentures, dental caps, or bridges depending on the materials from which they are made and other factors such as amount of saliva produced, possible interaction with denture adhesives, denture cleaning compounds, dryness of mouth and salivary constituents. Should an excessive degree of stickiness to dental work occur, there is the possibility that, as with other gums, Nicorette may damage dental work. If this should occur, the patient should discontinue its use and consult a physician or a dentist, as the case may require.

The severity of adverse reactions can sometimes be diminished by avoiding vigorous chewing.

### DOSAGE AND ADMINISTRATION:

Nicorette should be regarded as an adjunct to a pharmaceutical and psychological re-enforcer of a program to quit smoking, and not as a long-term nicotine substitute. Nicorette consumption should be terminated over a one or two week period after the smoking habit has been successfully broken.

However, it is strongly recommended that Nicorette pieces be carried by the patient for up to three months following cigarette abstinence in case a sudden overpowering urge to smoke occurs.

**Dosage 2 mg:** One 2 mg Nicorette piece to be chewed slowly in place of a cigarette when there is a craving to smoke. Up to 10 pieces per day is the usual recommended dosage although in exceptional cases, up to 20 pieces per day may be required.

**Dosage 4 mg:** One 4 mg Nicorette piece to be chewed slowly in place of a cigarette when there is a craving to smoke which is uncontrolled by 2 mg Nicorette.

### AVAILABILITY:

Nicorette is supplied as a 4 mg (pale yellow) and 2 mg (fawn colour) square of a highly-spiced, chewing resin, sweetened with sorbitol and packaged in blister pack strips of 15 pieces and contained in boxes of 7 strips (105 pieces).

Product monograph available on request.

Distributed by

Merrell Dow Pharmaceuticals (Canada) Inc.,  
380 Elgin Mills Road, East,  
Richmond Hill, Ontario, L4C 5H2

\*Trademark of AB LEO, Helsingborg, Sweden.



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