Recent Drug Therapy Issues

1. Androgens in the Aging Male
   True Hypogonadism – Treat; PADAM – Caution

2. Topical Corticosteroids on the Face (Pg 3)

3. Adverse Reaction Reporting (Pg 4)

May, 2003

Testosterone therapy in aging males has gained interest especially with advertising in the lay press and the resulting “pressure to prescribe”. Advertising often focuses on “body image” rather than clinical issues. The term “andropause” is misleading as men, unlike women, do not have a total reduction in hormone levels; however, levels of testosterone do generally decline with age. A more suitable term may be “partial androgen deficiency in the aging male” or PADAM. Symptoms overlap with age associated changes and other medical conditions (e.g. depression and hypothyroidism).

Table 1: Symptoms of Androgen Deficiency

<table>
<thead>
<tr>
<th>Symptom</th>
<th>CAUTION required in distinguishing true hypogonadism from symptoms naturally occurring with age (often multifactorial).</th>
</tr>
</thead>
<tbody>
<tr>
<td>↓ sexual desire and erectile quality</td>
<td></td>
</tr>
<tr>
<td>↓ changes in mood (depression, fatigue)</td>
<td></td>
</tr>
<tr>
<td>↓ lean body mass, muscle &amp; strength</td>
<td></td>
</tr>
<tr>
<td>↑ visceral fat</td>
<td></td>
</tr>
<tr>
<td>alterations in skin and body hair</td>
<td></td>
</tr>
<tr>
<td>↓ bone mineral density</td>
<td></td>
</tr>
</tbody>
</table>

As opposed to true hypogonadism, the decision to initiate androgen therapy in PADAM is subjective and controversial. Considerations include early morning testosterone levels (before ~9:30am) or preferably a “free androgen index”, severity of symptoms and a risk/benefit assessment. Testosterone levels have limitations given difficulties in interpretation and poor correlation between mildly low levels and symptoms. Symptom screening tools alone may result in a false positive diagnosis (up to 40% with the Morley Questionnaire). A trial of at least 3-6 months is required to differentiate true benefits from placebo effects. Long-term use depends on ongoing evaluation of clinical response, risk and assessment of testosterone levels.

Table 2: Controlled trials of testosterone (T) therapy in adult males with low-normal T levels (minimum 3 months duration; at least 40 subjects)

<table>
<thead>
<tr>
<th>Study</th>
<th>Size: Age</th>
<th>Duration</th>
<th>Therapy Studied</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janowsky</td>
<td>n=56; 67yr</td>
<td>3 month</td>
<td>T-scrotal patch (test) vs Placebo</td>
<td>↑ LBM &amp; ↓ in fat mass 12 13</td>
</tr>
<tr>
<td>Snyder</td>
<td>n=108; 73yr</td>
<td>36 month</td>
<td>T-scrotal patch (test) vs Placebo</td>
<td>BMD: ↑1 or no change 14; subanalysis found ↑BMD in d with T ≤ 6.9nmol/L 14</td>
</tr>
<tr>
<td>English</td>
<td>n=46; 62yr</td>
<td>3 month</td>
<td>T-transdermal patch  vs Placebo</td>
<td>Strength: no change 13; improvement in perception but not actual physical function 13</td>
</tr>
<tr>
<td>Kemp</td>
<td>n=67-14;76yr</td>
<td>12 month</td>
<td>T-transdermal patch (in d with coronary artery disease) vs Placebo</td>
<td>Sexual function: no change 15 or slight improvement 20</td>
</tr>
<tr>
<td>Kunelius</td>
<td>n=120; 58yr</td>
<td>6 month</td>
<td>DHT gel 125-250mg/d vs Placebo</td>
<td>CV; ↓ exercise induced angina &amp; pain 16</td>
</tr>
<tr>
<td>Wang</td>
<td>n=227; 51yr</td>
<td>3 &amp; 6 month</td>
<td>ANDROGEL 50mg/day vs ANDROGEL 100mg/day</td>
<td>Mood/energy/wellbeing: no effect 12, 19; ↑16</td>
</tr>
<tr>
<td>McNicholas</td>
<td>n=208; 58yr</td>
<td>3 month</td>
<td>T-gel 50mg/day (TESTIM) vs T-gel 100mg/day</td>
<td>Cognition: improved – spatial only 12</td>
</tr>
</tbody>
</table>

Adverse Effects

• ↑ PSA: usually small but consistent; generally no change IPSS or prostate weight (↑ PSA 10-21.2% 13; 17)
• ↑Hct >5% in 6-11% of pts 13, 22 Hgb
• HDL no change 15 or slight ↓18
• CV events: unknown (16 vs 9% for T vs Pl; p=0.25 NS) 15
• skin irritation: 77% Patch vs 40% Pl 17

To date trials are limited in that they have involved small numbers, been relatively short term (up to 3 years), and included healthy men with few or no signs of prostate disease (see Table 2). No trials are of significant size to provide reliable information on long-term cardiovascular or prostate outcomes. Large-scale trials are being considered. Given the limited evidence, androgen therapy of PADAM should be cautiously approached. Benefits may outweigh risks in patients with more severe symptoms of androgen deficiency. The recent Women’s Health Initiative (WHI) showed that predictions based on theoretical and observational data may not hold up in a well designed large-scale randomized clinical trial. Androgens Chart – Table 3
## TABLE 3 - Testosterone Agents [non-17-α-alkylated]

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th>Drug</th>
<th>Trade Name</th>
<th>Formulation</th>
<th>Usual Dosage Range (adult men androgen deficiency)</th>
<th>$ /30 days</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORAL</td>
<td>Testosterone undecanoate</td>
<td>ANDRIOL</td>
<td>40mg cap</td>
<td>80mg AM + 40mg PM</td>
<td>$108</td>
<td>- taking after meals greatly enhances absorption</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>80mg BID after meals</td>
<td>$142</td>
<td>- no effect on liver function over 10yrs (observation)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>40mg every other day</td>
<td>$ 25</td>
<td>- Storage: refrigerate in pharmacy; store at room temperature after dispensing (stable for 90 days)</td>
</tr>
<tr>
<td>TRANSDERMAL GEL</td>
<td>Testosterone 1% Gel (5g packet delivers 50mg testosterone &amp; approx. 10% absorbed)</td>
<td>ANDROGEL</td>
<td>2.5g, 5g packet</td>
<td>5g daily in AM initial dose $</td>
<td>$142</td>
<td>- applied to shoulder, abdomen or upper arms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10g daily in AM</td>
<td>$272</td>
<td>- patient should wait &gt;6hrs before showering, etc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>no effect on liver function over 10yrs (observation)$</td>
<td>$ 25</td>
<td>- possible transfer to partner: T-shirt before hugging</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>swelling without chewing</td>
<td></td>
<td>- gel generally better tolerated than patch</td>
</tr>
<tr>
<td>TRANSDERMAL PATCH</td>
<td>Testosterone (in alcohol based gel)</td>
<td>ANDRODERM</td>
<td>2.5mg, 5mg patch</td>
<td>2.5mg patch daily at HS</td>
<td>$142</td>
<td>- produces stable – normal testosterone levels</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5mg patch daily at HS</td>
<td>$142</td>
<td>- (8-12hrs after nightly application)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7.5mg patch daily at HS</td>
<td>$ 25</td>
<td>- skin irritation possible transfer to partner</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(Apply between 8 &amp; 12 PM)</td>
<td></td>
<td>- avoids bony areas; ROTATE site weekly</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- contact with water does not affect patch</td>
</tr>
<tr>
<td>INJECTABLE</td>
<td>Testosterone cyionate</td>
<td>DEPO-TESTOSTERONE</td>
<td>100mg/ml (10ml Vial)</td>
<td>100mg IM q2wks</td>
<td>$ 12</td>
<td>- supratherapeutic levels during first few days;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>150mg IM q2-3wks</td>
<td>$ 15</td>
<td>- subtherapeutic levels thereafter; .:more prone to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Alternating buttocks</td>
<td></td>
<td>- side effects such as mood disturbance, etc.</td>
</tr>
<tr>
<td></td>
<td>Testosterone enanthate</td>
<td>DELATESTRYL</td>
<td>[smaller injection volume advantage]</td>
<td>200mg/ml (5ml Vial)</td>
<td>$ 14</td>
<td>- testosterone levels: 7th day injection (mid range)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>150mg IM q2wks</td>
<td>$ 16</td>
<td>- range: 50mg q2wk – 200mg q2wk - 400mg q4wks</td>
</tr>
</tbody>
</table>

**DRUGS** for: alcohol, cimetidine, flutamide, glucocorticoids, ketoconazole, opioids, phenytoin, spironolactone; LIFESTYLE: smoking, stress, obesity; chronic medical conditions

**MEDICAL CONDITIONS**: hypothyroidism, hyperprolactinemia (drug induced or prolactinoma), Klenefelter’s syndrome, pituitary adenomas or tumors affecting pituitary (e.g. meningiomas, chromophobe adenomas)

**Related Conditions & Therapies**: DEPRESSION \(\rightarrow\) antidepressants, mood stabilizers; ERECTILE DYSFUNCTION \(\rightarrow\) VIAGRA, MUSE, other; OSTEOPOROSIS \(\rightarrow\) bisphosphonates, Ca**+** & Vitamin D; HYPOTHYROIDISM \(\rightarrow\) levothyroxine; LIBIDO \(\rightarrow\) multifactorial; LIFESTYLE \(\rightarrow\) exercise, diet, sleep, avoid excess alcohol & caffeine, positive social support/relationships

**TABLE 4: Potential BENEFITS of Androgen Therapy**

- ↓↓ body fat; ↑ lean body mass (LBM)
- ↑ body density; ↑ lean body mass; ↓ fat on fracture outcomes
- ↑ hand-grip strength; ↑ less effect on lower body
- ↓ bone density; ↓ lack of data on fracture outcomes
- ↑ testosterone levels (preliminary data)
- ↑ libido; possible improvement in sexual function (improvement specifically seen in men with very low/lowest of testosterone levels)
- HIV/AIDS patients: improved quality of life, ↑ LBM

**TABLE 5: Potential RISKS of Androgen Therapy**

- **Cardiovascular - HDL**: long-term effects unknown
- **Fluid retention**: exacerbation of heart failure
- **Polythemia** (↑Hgb; ↑Hct) – ↑ stroke risk; less with oral/transdermal forms which provide stable levels
- **Gynaecomastia** (especially if hepatic/renal disease)
- **Prostate**: ↑ prostate size; ↑ PSA but usually within normal range; possible acceleration of prostate cancer
- **Difficulty with urination - 2°**: to benign prostatic hypertrophy (one study found retardation in BPH)
- **Sleep apnea**: may exacerbate pre-existing sleep apnea; ↓ in obese, smokers, COPD
- **Other**: acen: exacerbation of aggression, hostility inappropriate sexual behavior or psychotc illness

**TABLE 6: MONITORING of Androgen Patients**

- **Clinical evaluation** of symptom response and side effects (from patient and/or spouse or family member)
- **Prostate assessment**: baseline & annually; some references suggest more frequent in first year
- **Questionnaire regarding urinary/prostate symptoms**
- **Digital rectal exam (DRE) & PSA**: range: 0-4 ng/L
- **Lab Tests**: Hct, Hgb, Liver Function Tests
- **CV assessment**: lipid profile, edema, weight gain
- **Testosterone level**: normal = 6-29nmol/L (UK Peer Lab) *Free Androgen Index* \(\rightarrow\) provides better measure of bioavailable testosterone (normal $\delta = 14.8-94.8$); (accounts for effect of sex hormone binding globulin [SHBG])
Recent Drug Therapy Issues

2. Topical Corticosteroids on the Face – the Cure Becomes the Problem!

Topical corticosteroids on the face often produce local side effects, including atrophy, steroid acne, perioral dermatitis, hypertrichosis, hypopigmentation, rosacea, glaucoma, striae, telangiectasia and superinfections. Steroid-induced rosacea with facial use of mid-high potency steroids has been reported, thus we are strengthening our cautionary statement in the corticosteroid chart. Even the lowest potency topical steroids induced rosacea in a study of 106 children. This study and a recent review recommended abrupt withdrawal of topical steroids and treatment of the rosacea. A severe rebound “flare-up” would be expected, usually in 4-10 days and lasting up to 3 weeks. Treatment depends on the stage: antibiotics (oral: tetracycline/doxycycline, adults or erythromycin children; topical: metronidazole or clindamycin preferred in pregnancy), retinoids, atenolol, clonidine, tacrolimus, surgery or laser therapy. Treatment of unresponsive steroid-induced rosacea with ≤ 10 days of tacrolimus (PROTOPIC 0.03-0.1% ointment BID ~$84/month, EDS Sask) or possibly pimecromelactone (ELIDEL 1% cream BID ~$72/month, non formulary Sask) appears promising. These new agents may cause less skin atrophy, less rebound “flare-up”, but may cause some skin burning, itching, and an increased risk of infection. See previous review - RxFiles – May 98.

**BOTTOM LINE:** In general, only low potency topical corticosteroids should be used on the face and only for a limited time.

### Topical Corticosteroid Creams: Comparison Chart

<table>
<thead>
<tr>
<th>DRUG/STRENGTH</th>
<th>BRAND NAME</th>
<th>POTENCY &amp; $</th>
<th>SIZE / COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betamethasone dipropionate 0.05%</td>
<td>Diprolene Glycol, Toplène Glycol</td>
<td>$26</td>
<td>High Potency agents: reserve for resistant conditions/ thick skin areas due to potential for local &amp; systemic side effects. <strong>Ultra Potent agents:</strong> max ~50g/week; <em>limit duration</em>; apply OD-BID; 15,50,450g PG, PB, PG, PG</td>
</tr>
<tr>
<td>Clobetasol propionate 0.05%</td>
<td>Dermovate, Others</td>
<td>$22</td>
<td>15,50, PG, PG</td>
</tr>
<tr>
<td>Desoximetasone 0.25%</td>
<td>Topicort, Desoxi</td>
<td>$23</td>
<td>20,60g PG, PG</td>
</tr>
<tr>
<td>Fluocinonide 0.05%</td>
<td>Lidex, Lyderm</td>
<td>$24</td>
<td>15,60g PG, PG</td>
</tr>
<tr>
<td>Halcinonide 0.1%</td>
<td>Halog</td>
<td>$26</td>
<td>15,30,60g PG</td>
</tr>
<tr>
<td>Halobetasol propionate 0.05%</td>
<td>Ultravate</td>
<td>$33</td>
<td>Exception Drug Status in Sask. 15,50,450g PG, PG, PG</td>
</tr>
<tr>
<td>Betamethasone dipropionate 0.05%</td>
<td>Diprosone, Taro-Sone</td>
<td>$15</td>
<td>15,30,60g OH, PG, PG</td>
</tr>
<tr>
<td>Amincinoide 0.1%</td>
<td>Clocycort (lanolin,paraben,PG, tartrazine, urea free)</td>
<td>$25</td>
<td>15,30,60g OH, PG, PG</td>
</tr>
<tr>
<td>Betamethasone dipropionate 0.025%</td>
<td>Propaderm</td>
<td>$28</td>
<td>15,45g PG, PG</td>
</tr>
<tr>
<td>Clobetasol butyrate 0.05%</td>
<td>Eumovate</td>
<td>$22</td>
<td>15,30g PG, PG</td>
</tr>
<tr>
<td>Desoximetasone 0.05%</td>
<td>Topiport Mild, Desoxi</td>
<td>$17</td>
<td>20,60g PG, PG</td>
</tr>
<tr>
<td>Diflucortolone valerate 0.1%</td>
<td>Nerison Oily Cr</td>
<td>$21</td>
<td>30g PG, PG, PG</td>
</tr>
<tr>
<td>Mometasone furoate 0.1%</td>
<td>Elocom (once daily recommended)</td>
<td>$30</td>
<td>15,50,100g PG, PG, PG</td>
</tr>
<tr>
<td>Triamcinolone acetonide 0.1%</td>
<td>Kenalog, Triaderm, Aristocort-R</td>
<td>$13</td>
<td>15,30,50g PG, PG, PG</td>
</tr>
<tr>
<td>Betamethasone valerate 0.1% 0.05%</td>
<td>Betaderm, Celestoderm-V, Ectosone Mild</td>
<td>$8</td>
<td>15,50,450g PG, PG, PG</td>
</tr>
<tr>
<td>Fluocinolone acetonide 0.025% 0.01%</td>
<td>Fluoderm regular, Fluoderm mild</td>
<td>$19</td>
<td>15,000g PG, PG, PG, PG</td>
</tr>
<tr>
<td>Hydrocortisone valerate 0.2%</td>
<td>Westcort, Hydroval</td>
<td>$14</td>
<td>15,45,60g PG, PG, PG, PG</td>
</tr>
<tr>
<td>Triamcinolone acetonide 0.025%</td>
<td>Triaderm</td>
<td>$9</td>
<td>15,30,50g PG, PG, PG</td>
</tr>
<tr>
<td>Desonide 0.05%</td>
<td>Desocort, Trinidad</td>
<td>$17</td>
<td>15,60g PG, PG, PG, PG</td>
</tr>
<tr>
<td>Hydrocortisone/Urea 1%/10%</td>
<td>Uremol-CH</td>
<td>$14</td>
<td>50,225g PG 15°C, OD-QID, low cost</td>
</tr>
<tr>
<td>Hydrocortisone 2.5% 1% 0.5% (OTC)</td>
<td>Emo-Cort, Cortate, Hydram, Emo-Cort</td>
<td>$15</td>
<td>45,225g OTC PG, PG, PG, PG, PG</td>
</tr>
</tbody>
</table>

### Potency *Classification - Ultra high steroid potencies are up to 1000 times more potent than hydrocortisone

**Group 1 = Ultra High Potency**
- *reserve for resistant conditions; high potential for serious side effects (local & systemic)*
- *suitable for short term intermittent use in severe eczematous dermatoses and psoriasis*
- *often required for palms, soles, & scalp where thickened skin may require prolonged Tx*
- *generally limit to OD-BID, & length of Tx. to 2-4 weeks followed by less potent agent* (See previous review - RxFiles – May 98)
- *avoid use on large areas, thin skin areas, skin folds, in young children/infants, face*
- *avoid on thin skin areas; extreme caution if used on face, intertriginous areas (severe adverse effects)*
- *safe* for use in children, infants, & elderly or when covering large or higher risk areas (face, eyelids, skin flexures, scrotum); **CAUTION** still required! *suitable for maintenance of most chronic conditions after initial control obtained*; *often applied BID-QID; apply less frequent (OD-BID) if ongoing use*

**Group 2 = High Potency**
- *suitable for intermediate long term use, chronic use in thick skin areas (hand eczema)*
- *suitable for intermittent use, chronic use in thick skin areas (hand eczema)*

**Group 3 = Moderate Potency**
- *suitable for long term use, chronic use in thick skin areas (hand eczema)*
- *suitable for use in children, infants, & elderly or when covering large or higher risk areas (face, eyelids, skin flexures, scrotum); CAUTION still required! *suitable for maintenance of most chronic conditions after initial control obtained*; *often applied BID-QID; apply less frequent (OD-BID) if ongoing use*

**Group 6,7 = Low Potency**
- *suitable for use in children, infants, & elderly or when covering large or higher risk areas (face, eyelids, skin flexures, scrotum); CAUTION still required! *suitable for maintenance of most chronic conditions after initial control obtained*; *often applied BID-QID; apply less frequent (OD-BID) if ongoing use*
Did you know??

- 51% of newly approved drugs have serious adverse effects that are undetected at the time of marketing.\[4\]
- 3-7% of hospital admissions are due to adverse reactions, and 1.5-35% of patients experience a 2nd reaction during hospital stay.\[5, 55-58\]
- Adverse reactions are reported in: 6% of patients taking 1-3 medications and in 52% of patients taking 8 or more medications.\[6\]
- The reported incidence of adverse reactions in ambulatory patients varies from 3-68%.\[7, 8\]
- A study done by Canadian investigators at the University of Toronto showed serious ARs result in 76,000-137,000 deaths annually in the United States, making ARs the 4th to 6th leading U.S. cause of death.\[9\]

Why is it important to document adverse reactions?

- Knowledge of drug risk evolves over the lifetime of the drug and therefore risk assessment must continue beyond the pre-market evaluation phase.
- Populations used in clinical trials are not representative of the population as a whole. “Clinical trials evaluate drugs rather than patients or diseases.”\[10\]
- Spontaneous, voluntary reporting programs (e.g. SaskAR) serve as “early warning systems” for rare and unexpected reactions. These programs have been credited with identification of thromboembolic complications with oral contraceptives, withdrawal reactions to paroxetine, hepatotoxicity with nefazodone, and drug interactions with grapefruit juice.
- Case reports are reviewed and entered onto national and international databases that are constantly monitored for signals. Serious, unlabelled effects, if reported, become known very quickly allowing for timely notification of health care professionals.

What is an Adverse Reaction (AR)?

Health Canada defines an AR as “a noxious and unintended response to a drug which occurs with use or testing for the diagnosis, treatment, or prophylaxis of a disease or modification of an organic function. This includes any undesirable patient effect suspected to be associated with drug use. ARs resulting from any prescription, non-prescription, biological (including blood products), complementary medicines (including herbal), and radiopharmaceutical drug products are monitored.”\[11\]

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AR reports are, for the most part, only SUSPECTED associations! Reporting an AR does not imply a causal link.

What kind of adverse reactions should I report?

A temporal or possible association is sufficient for a report to be submitted.

The following suspected reactions should be reported:

- Reactions to Recently Marketed Drugs includes drugs that have been marketed within the last 5 years. All reactions, regardless of nature or severity, should be reported as these drugs have limited post-marketing experience.
- Serious Reactions includes reactions that result in hospitalization or prolong existing hospitalization, results in congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.
  - report serious reactions when they occur even if all details are not known. Follow-up information can be submitted when it becomes available.
- Unexpected Reactions includes reactions (regardless of severity) which are not consistent with product labeling. These reactions are often NOT explainable pharmacologically.

**REPORTING AN ADVERSE REACTION**

Reports can be submitted in writing (i.e. by mail or fax) or verbally by telephone (Hours: Monday-Friday, 0830-1630).

- **FAX - Kazakhstan** 306-966-2286
- **FAX - Toll-free Canada** 1-866-678-6789
- **Telephone - Kazakhstan** 306-966-6329
- **Telephone - Toll-free Canada** 1-866-234-2345

Report forms are available in:

- Compendium of Pharmaceuticals & Specialties (CPS)
- Saskatchewan Prescription Drug Plan Formulary Appendix
  - Click on “Report (form) of suspected adverse reaction due to drug products marketed in Canada”. Form can be downloaded, printed, completed and sent.

If you have any comments or questions, or if you would like to report an adverse reaction, please contact us:

SaskAR Regional Centre, Saskatchewan Drug Information Service (SDIS), College of Pharmacy & Nutrition, 110 Science Place, University of Saskatchewan, Saskatoon SK S7N 5C9
  - Telephone: Saskatoon 306-966-6329; Toll-free 1-866-234-2345

Physician, reporter & patient confidentiality is ensured.

Regular advisories by Health Canada can be obtained from [http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advss_tpd_bqld_e.html](http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advss_tpd_bqld_e.html)

Email service provides link to free advisories upon posting.
Canadian Adverse Drug Reaction Monitoring Program

Report of suspected adverse reaction
due to drug products marketed in Canada
(Vaccines excluded)

A. Patient Information
1. Patient identifier
   Chart Number
   Date of birth
   DD MM YYYY
2. Age at time of reaction
3. Sex
   Male
   Female
4. Height
   _______ cm
5. Weight
   _______ lbs

B. Adverse Reaction
1. Outcome attributed to adverse reaction (check all that apply)
   □ Death (dd / mm / yyyy)
   □ Disability
   □ Life-threatening
   □ Congenital malformation
   □ Hospitalization
   □ Required intervention to prevent damage / permanent impairment
   □ Hospitalization - prolonged
   □ Other: ____________________________

2. Date and time of reaction
   DD MM YYYY
3. Date of this report
   DD MM YYYY
4. Describe reaction or problem
5. Relevant tests / laboratory data (including dates (dd / mm / yyyy)

6. Other relevant history, including preexisting medical conditions
   (e.g. allergies, pregnancy, smoking and alcohol use, hepatic / renal dysfunction)

C. Suspected drug product(s)
(See "How to report" section on reverse)
1. Name (give labeled strength & manufacturer, if known)
   #1
   ________________________________
   #2

2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration)
   #1 From (dd / mm / yyyy) - To (dd / mm / yyyy)
   #2

4. Indication for use of suspected drug product
   #1
   #2

5. Reaction abated after use stopped or dose reduced
   #1 Yes No Doesn't apply
   #2 Yes No Doesn't apply

6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1 (dd / mm / yyyy)
   #2

8. Reaction reappeared after reintroduction
   #1 Yes No Doesn't apply
   #2 Yes No Doesn't apply

9. Concomitant drugs (name, dose, frequency and route used) and therapy dates
   (dd / mm / yyyy) (exclude treatment of reaction)

10. Treatment of adverse reaction (drugs and / or therapy), including dates
    (dd / mm / yyyy)

D. Reporter
(See "Confidentiality" section on reverse)
1. Name, address & phone number.

2. Health professional?
   ☐ Yes ☐ No

3. Occupation

4. Also reported to manufacturer?
   ☐ Yes ☐ No

For TPP use only

HCSC 4016 (12-98)