Complete Summary

GUIDELINE TITLE

Management of urinary incontinence in primary care. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of urinary incontinence in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Dec. 41 p. (SIGN publication; no. 79). [128 references]

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta (duloxetine hydrochloride), indicated for treatment of major depressive disorder and diabetic peripheral neuropathic pain. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with any hepatic insufficiency. See the FDA Web site for more information.

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SCOPE

DISEASE/CONDITION(S)

Urinary incontinence, including:

- Stress urinary incontinence
- Urge urinary incontinence
- Detrusor overactivity incontinence
- Mixed urinary incontinence

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Nursing
Obstetrics and Gynecology
Urology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Patients
Physical Therapists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To identify opportunities and effective techniques within primary care for assessing and treating urinary incontinence in adults
- To offer the primary care practitioner an indication of the factors that should lead to an onward referral

TARGET POPULATION

Adults with urinary incontinence

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Risk factor assessment
2. Assessment via:
    - Clinical history
    - Questionnaires
    - Pelvic floor assessment
    - Urinalysis
    - Post void residual volume (via catheterization and/or ultrasound bladder scan)
    - Flow rate
    - Digital rectal examination
    - Voiding diaries
    - Pad tests

Management/Treatment

1. Client counseling regarding treatment options
2. Pelvic floor muscle exercises (PFME)
3. Physiotherapy
4. Biofeedback
5. Electrical stimulation
6. Intravaginal devices
7. Acupuncture
8. Bladder retraining
9. Lifestyle interventions including massive (surgically induced) weight loss, moderate weight loss, adjustment of fluid intake, and reduce caffeine intake
10. Pharmacotherapy
    - Combined noradrenaline and serotonin reuptake inhibitors: Duloxetine
    - Antimuscarinics (oxybutynin, tolterodine, trospium and propiverine)
    - The following medications were discussed but not recommended: flavoxate; oestrogens; adrenoreceptor agonists; antidepressants
11. Containment products including disposable pads, bed pads, sheaths, female urinals, catheters, catheter valves, and urine drainage bags
12. Referral to secondary care, when appropriate

MAJOR OUTCOMES CONSIDERED

- Incontinence episode frequency and severity
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base for this guideline was synthesised in accordance with the Scottish Intercollegiate Guideline Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by the SIGN Information Officer in collaboration with members of the guideline development group.

Literature searches were initially conducted in Medline, Embase, Cinahl, and the Cochrane Library using the year range 1995–2003. The literature search was updated to cover the period up to May 2004. Key Web sites on the Internet were also used, such as the National Guidelines Clearinghouse. These searches were supplemented by the reference lists of relevant papers and group members' own files. The Medline version of the main search strategies can be found on the SIGN website.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g. case reports, case series)

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. Scottish Intercollegiate Guidelines Network has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines" (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the groups are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are <u>not</u> an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held on 24th November 2003 and was attended by 168 representatives of all the key specialties relevant to the guideline. The draft guideline was available on the SIGN Web site for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The guideline was also reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and

accuracy of interpretation of the evidence base supporting the recommendations in the guideline.

As a final quality control check, the guideline is reviewed by an Editorial Group to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.

Each member of the guideline development group then approved the final guideline for publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

The strength of recommendation grading (A-D) and level of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Quality of Life, Patient Information, and Health Promotion

Quality of Life

Objective Assessment

B - Health care practitioners should consider using a validated quality of life and incontinence severity questionnaire to evaluate the impact of urinary symptoms and to audit the effectiveness of any management strategy.

Patient Information, Advice, and Support

D - Patients with urinary incontinence should be offered information and advice on the treatment options available to them in both primary and secondary care.

D - Patients with urinary incontinence should have access to trained health care professionals who have the relevant knowledge and skills to offer appropriate advice and information.

D - Patients with urinary incontinence should be made aware that they are able to access specially trained staff in primary care without general practitioner (GP) referral.

Health Promotion

C - Strategies using a number of different approaches and delivery media should be employed to raise awareness of urinary continence and promote incontinence services to a range of target audiences.

Assessment of Urinary Incontinence

Risk Factors for Developing Urinary Incontinence

Risk Factors for Women

B - Health professional should be vigilant and adopt a proactive approach in consultations with patients who are at greatest risk of developing urinary incontinence through factors including age, the menopause, pregnancy and childbirth, high body mass index (BMI), and experience of continence problems in childhood.

Initiating an Assessment of Urinary Incontinence

C - Health care professionals should recognize the difficulty that some patients have in raising concerns about continence and should be proactive in questioning patients about continence during consultations.

C - Health professional should have a positive attitude to continence problems.

B - Assessment, treatment, and referral, as appropriate, should be offered to all patients with urinary continence problems.

Primary Care Assessment Tools

Assessment Tool Recommendations

D - Initial assessment of a male patient with urinary incontinence should include completion of a voiding diary, urinalysis, estimation of post void residual volume, and digital rectal examination.

D - Initial assessment of a female patient with urinary incontinence should include completion of a voiding diary, urinalysis, and, where symptoms of voiding dysfunction or repeated urinary tract infections (UTIs) are present, estimation of post void residual volume.

Physical Therapies

Pelvic Floor Muscle Exercises

A - Pelvic floor muscle exercises should be the first choice of treatment offered to patients suffering from stress or mixed incontinence. Exercise programmes should be tailored to be achievable by the individual patient.

D - Pelvic floor muscle exercises should be considered as part of a treatment plan for patients with urge urinary incontinence.

D - Digital assessment of pelvic floor muscle function should be undertaken prior to initiating any pelvic floor muscle exercise treatment.

A - Where group physiotherapy is available patients should be offered the choice of attending or being seen individually.

Pelvic Floor Muscle Exercises in Men Undergoing Radical Prostatectomy

B - Pelvic floor muscle exercise treatment should be considered for patients following radical prostate surgery.

Bladder Retraining

C - Bladder retraining should be offered to patients with urge urinary incontinence.

Pharmacotherapy

Stress Incontinence

Combined Noradrenaline and Serotonin Reuptake Inhibitors

A - Duloxetine should be used only as part of an overall management strategy in addition to pelvic floor muscle exercises and not in isolation. A 4-week trial of duloxetine is recommended for female patients with moderate to severe stress incontinence. Patients should be reviewed again after 12 weeks of therapy to assess progress and determine whether it is appropriate to continue treatment.

Detrusor Overactivity and Urge Incontinence

Antimuscarinics

A - A trial of oxybutynin, propiverine, tolterodine, or trospium should be given to patients with significant urgency with or without urge incontinence. The dose should be titrated to combat adverse effects.

Containment

Product Evaluation

D - All patients should undergo a continence assessment before product issue. Issue of products should not take the place of therapeutic interventions.

Referral

Referral to Secondary Care

All Patients

D - Patients should be referred to secondary care if previous surgical or non-surgical treatments for urinary incontinence have failed or if surgical treatments are being considered.

Female Patients

D - Female patients with suspected voiding dysfunction should be referred to secondary care.

D - Female patients with symptomatic pelvic organ prolapse should be referred to secondary care.

Male Patients

D - Male patients with reduced urinary flow rates or elevated post void residual volumes should be referred to secondary care.

Definitions:

Levels of Evidence

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4: Expert opinion

Grades of Recommendation

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Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for the management of urinary incontinence in male patients and in female patients.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective treatment and management of urinary incontinence resulting in reduced incontinence episode frequency, reduced urgency, increased patient satisfaction, improved quality of life, and reduced incidence of potential harms (e.g., falls and fractures).

POTENTIAL HARMS

- There are inherent risks of trauma and infection with catheterisation and there may be issues around patient dignity and acceptability that should be considered.
- Side effects of adrenoreceptor agonists were noted to be minor, although rare and potentially serious side effects, such as cardiac arrhythmias and hypertension, were reported.
- Nausea was the most commonly reported adverse event in one study of duloxetine.
- The most common side effects of antimuscarinic drugs are dry mouth, blurred vision, abdominal discomfort, drowsiness, nausea, and dizziness. Urinary

retention is a potentially serious but less common side effect. Oxybutynin immediate release (IR) preparation has the highest incidence of side effects.
- Offering disposable pads prematurely can lead to psychological dependence upon them and reluctance to accept active treatment.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the appropriate health care professional, following discussion of the options with the patient, in light of the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.
- The guideline cannot take the place of clinical judgment in the assessment of each patient as an individual but aims to collate research evidence, in as accessible format, to support clinical decision making.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of local National Health Service (NHS) organisations and is an essential part of clinical governance. It is acknowledged that not every guideline can be implemented immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Implementation in Primary Care

The Scottish Programme for Improving Clinical Effectiveness in Primary Care (SPICE-PC) will develop a criteria set based on this guideline to assist with its implementation in primary care. The criteria set will be incorporated into a GPASS care management screen, combining computer based management prompts with appropriate, automated data collection. SPICE-PC criteria sets are available from www.ceppc.org/spice/criteria.shtml.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of urinary incontinence in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Dec. 41 p. (SIGN publication; no. 79). [128 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Dec

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Mrs Linda Morrow (Chair) Professional Adviser Continence, The Care Commission, Musselburgh; Mrs Joyce Wilkinson (Secretary) Registered Health Visitor, Doctoral Candidate, University of St. Andrews; Mrs Mary Ballentyne, Senior Clinical Nurse Specialist, Southern General Hospital, Glasgow; Mrs Mary Brown, Continence Nursing Team Manager, Lothian Primary Care Trust, Edinburgh; Ms Jane Camp, Clinical Governance Practice Development Nurse, Gartnavel Royal Hospital, Glasgow; Dr Paul Dewart, Consultant Obstetrician/Gynaecologist, St. John's Hospital, Livingston; Mrs Ann Gilchrist, Superintendent Physiotherapist/Clinical Lead, Falkirk Royal Infirmary; Sister Chris Harris, Urology Nurse Specialist, Western General Hospital, Edinburgh; Mrs Linda Haworth, Superintendent Physiotherapist/Clinical Specialist, Carnegie Clinic, Dunfermline; Ms Fiona Lamont, Patient Representative, Glasgow; Mr David Lyth, Consultant Urologist, Queen Margaret Hospital, Dunfermline; Mrs Jan MacCallum, Continence Adviser, Broxburn, West Lothian; Dr David Marshall, Professional Adviser-Pharmacy, The Care Commission, Hamliton; Ms Cathy McKerrell, INCONTACT Project Manager (Scotland); Dr Simon Nicholson, Consultant Gynaceologist, St John's Hospital, Livingston; Mr Duncan Service, Senior Information Officer, SIGN; Dr Lorna Thompson, Programme Manager, SIGN

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) executives.

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Quick reference guide: Management of urinary incontinence in primary care. Scottish Intercollegiate Guidelines Network. 2004 Dec. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.

Additional implementation tools, including an incontinence questionnaire and a sample frequency voiding volume chart/voiding diary can be found in the Annexes of the original guideline document.

PATIENT RESOURCES

The following is available:

- Information for discussion with patients and carers. In: Management of urinary incontinence in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Dec. 41 p. (SIGN publication; no. 79).

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on March 3, 2005. The information was verified by the guideline developer on March 17, 2005. This summary was updated by ECRI on October 20, 2005, following the U.S. Food and Drug Administration advisory on Cymbalta (duloxetine hydrochloride).

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