

# medicineupdate

Asking the right questions about new medicines

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## Duloxetine (Cymbalta) for major depression

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*get to know your medicines*

### to find out more about this medicine

- call Medicines Line on 1300 888 763 to speak to a pharmacist (Mon–Fri 9am–6pm EST — cost of a local call, mobile calls more)
- read the Consumer Medicine Information (CMI) leaflet for this medicine (available from your doctor or pharmacist, from the consumer section at [www.nps.org.au](http://www.nps.org.au), or from the manufacturer).



National Prescribing Service Limited

NPS is an independent, non-profit organisation for Quality Use of Medicines, funded by the Australian Government Department of Health and Ageing.

## Summary

Duloxetine is a new antidepressant which we believe to be as effective as, but no better than, any other antidepressant. Its side effects are not fully known. It may be useful for some people. The choice of which antidepressant to use depends on many factors, including:

- the type of depression you have
- your general health and medical condition
- your current medications
- how important different side effects may be to you.

While antidepressants are a helpful part of treatment for many people, psychological treatments and other non-drug elements (e.g. exercise, sleep) play an important role in managing depression, whether or not medicines are used.

When you are considering a new medicine, it is important to weigh up the expected benefits and the possible risks of that new medicine, compared with other available medicines or treatments.

Remember that risks and benefits differ between medicines and from person to person.

Your doctor can help you compare different medicines and treatments to decide what is best for your particular situation.

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### 1. What this medicine is

The active ingredient is **duloxetine**, pronounced due-LOKS-e-teen.

The brand name is **Cymbalta**, pronounced sim-BAL-tah.

The active ingredient is the chemical in the medicine that makes the medicine work.

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### 2. What this medicine treats

Duloxetine treats major depressive disorder, or major depression.

Major depressive disorder is not simply a case of the blues. It is a serious illness which involves some or all of the following symptoms most of the time:

- feeling down
- sleeping badly
- losing interest in things you normally enjoy
- losing or gaining weight
- having difficulty moving
- being very tired
- feeling guilty
- finding it hard to concentrate
- having thoughts of death.

Not all major depressions are the same — there are different types. People with a particular type of major depression may be more likely to benefit from one type of antidepressant than another. But there are no hard and fast rules. For some people, getting on the right antidepressant is a matter of using one, giving it 6 weeks, and changing it if it does not help. All this requires close medical supervision — do not start, change or stop antidepressants without medical advice.

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**3.**  
**How this  
medicine works**

Duloxetine is thought to work by affecting the balance of different chemicals in the brain.

Like all antidepressants, duloxetine takes time to work. It may take 2–3 weeks to have its full effect. It works best if used for 6 months or longer.

Like all antidepressants, duloxetine works in about half the people who use it. For the rest, it will have no benefit.

It may take time to find the best antidepressant for you.

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**4.**  
**Who can use  
this medicine**

You can use this medicine if you have been diagnosed with depression and are prescribed it by a doctor.

Do not use duloxetine if you are under 18 years. Do not use anybody else's duloxetine, and do not give yours to anybody else.

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**5.**  
**Other medicines  
available for this  
condition**

Many other medicines are available to treat major depression. They all work by affecting the balance of chemicals in the brain, which are believed to contribute to the physical and psychological symptoms of depression.

These antidepressants are all about as effective as each other. But some people will benefit from one antidepressant, and not another. It is difficult to predict who may benefit from which medicine.

Antidepressants can be grouped as follows.

**Selective serotonin reuptake inhibitors (SSRIs)**

SSRIs have been available for more than 20 years. They are the most commonly used antidepressants. They are no more effective than others, but usually cause fewer side effects. They include citalopram (e.g. Celapram), escitalopram (e.g. Lexapro), fluoxetine (e.g. Prozac), fluvoxamine (e.g. Luvox), paroxetine (e.g. Aropax) and sertraline (e.g. Zoloft).

**Serotonin and noradrenaline reuptake inhibitors (SNRIs), which includes duloxetine**

SNRIs are a slightly newer class of medicines. The first one available was venlafaxine (Efexor). Duloxetine is an SNRI like venlafaxine.

**Tricyclic antidepressants**

Tricyclic antidepressants have been available for more than 40 years. They include amitriptyline (e.g. Endep), clomipramine (e.g. Anafranil), dothiepin (e.g. Prothiaden), doxepin (e.g. Sinequan), imipramine (e.g. Tofranil), nortriptyline (e.g. Allegron) and trimipramine (e.g. Surmontil). Tricyclic antidepressants are just as effective as SSRIs and SNRIs, but they usually cause more side effects.

**Other antidepressants**

Other antidepressants include mianserin (Tolvon), mirtazapine (e.g. Avanza), moclobemide (e.g. Aurorix), reboxetine (e.g. Edronax), phenelzine (Nardil) and tranylcypromine (Parnate).

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**Talk with your doctor about all of the treatment options for major depression. They include not just medication, but also lifestyle changes, counselling and electroconvulsive therapy (for very severe depression). See section 11 for details.**

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**6.**  
**How well it works compared with other medicines**

Clinical trials indicate that duloxetine is as effective as some other antidepressants in reducing depression. There is no evidence to say duloxetine is better than other antidepressants.

It may be worth trying duloxetine if your symptoms have not improved with other antidepressant medicines. However, there is no reason to believe it will be more effective than other medicines whose benefits and side effects are better known.

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**7.**  
**Important side effects to consider**

Duloxetine is a new medicine to Australia, but has been available in the US and the UK for several years.

The side effects that have most commonly shown up in clinical trials of duloxetine include nausea (especially when starting to use the medicine), constipation, trouble sleeping and dizziness. Some people may have no side effects.

Other side effects to be aware of include headaches and loss of sex drive. Duloxetine may increase blood pressure slightly.

**For a list of possible side effects, see the Consumer Medicine Information leaflet for Cymbalta.**

**Talk to your doctor about the possible side effects of this medicine before you use it.**

**Always tell your doctor about any changes to your condition if you are taking a new medicine.**

**More information on understanding side effects is available from the Australian Self-Medication Industry at [www.asmi.com.au/QUM.htm#sideeffects](http://www.asmi.com.au/QUM.htm#sideeffects).**

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**8.**  
**How these side effects compare with other medicines**

Side effects will be considered in the groups described in section 5.

**Selective serotonin reuptake inhibitors (SSRIs)**

SSRIs commonly cause nausea, agitation, trouble sleeping, drowsiness and sexual difficulties.

**Serotonin and noradrenaline reuptake inhibitors (SNRIs)**

Venlafaxine has similar side effects to duloxetine — nausea (especially when starting to use the medicine), constipation, trouble sleeping and dizziness. Both medicines may also increase blood pressure slightly.

**Tricyclic antidepressants**

Tricyclic antidepressants commonly cause sleepiness, a dry mouth, blurred vision, constipation and weight gain.

*continued next page ...*

**All antidepressants have some significant and potentially serious side effects and others that are less serious. The side effects differ between antidepressants and between people — some people get very few side effects. You need to discuss your health and any other conditions with your doctor when considering antidepressants.**

... continued

**8.**  
**How these side effects compare with other medicines (continued)**

**Others**

Phenelzine (Nardil) and tranylcypromine (Parnate) may cause low blood pressure, sleeping problems, headaches and drowsiness. They should be avoided, if possible, by people with heart disease or who have had a stroke. A special diet (avoiding, for example, cheese and red wine) must be adhered to.

**Discuss with your doctor the benefits and risks of taking (and not taking) antidepressants.**

**Side effects with most or all antidepressants**

For all people taking antidepressants, there is also the risk of suicidal thoughts. These occur more often than usual in the period soon after people start taking antidepressants, partly because people starting to use antidepressants are at a very low point. If suicidal thoughts do get worse, then seek help urgently from your GP, psychiatrist, local hospital or Lifeline (call 13 11 14).

Is it the medicine or is it the depression? This difficult question exists for many side effects. Trouble sleeping — is that the depression or the medicine? Loss of sexual function — depression or medication? Sometimes it can be difficult to tell, but you should discuss any problems that worry you with your GP or psychiatrist.

Most antidepressants interact with other medications — you need to discuss with your doctor all the medicines you use, including herbal and natural medicines.

If you are pregnant, breastfeeding or thinking about becoming pregnant, side effects become even more important. You should ask for specialist advice about medicines, either directly or through your GP or antenatal clinic.

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**9.**  
**How to reduce your risk of side effects**

There are a number of ways to reduce your risk of side effects when taking duloxetine.

If you get an upset stomach, try taking duloxetine with food.

Avoid alcohol or minimise the amount you drink — alcohol and duloxetine don't mix well.

It is also important to see your doctor 6 weeks after starting it, and discuss stopping it if it isn't working.

But the most important things to consider are how to start the medicine and how to stop it.

Many people find nausea and some other side effects are worse when starting the medicine. The nausea usually settles down within the first week. These side effects can be reduced by taking a smaller dose for the first week. However, a lower dose for the first week may delay the medicine becoming fully effective.

Stopping duloxetine suddenly can also cause side effects. Do not stop duloxetine suddenly — the dose should be reduced gradually over a period of weeks.

Even when coming off the medicine gradually, some people will find they have trouble sleeping and may feel dizzy, nauseous or anxious. These effects will usually pass within a week or two.

**Your doctor or pharmacist should be able to help with advice on how to reduce the risk of side effects.**

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**10.**  
**What else you should know about this medicine**

The Consumer Medicine Information leaflet available for Cymbalta will tell you:

- who should and who should not use the medicine
- which medicines should not be used while taking duloxetine
- how to use the medicine
- the most likely side effects
- the ingredients.

You can get the Consumer Medicine Information leaflet for Cymbalta from:

- your doctor or pharmacist
- [www.nps.org.au/consumers](http://www.nps.org.au/consumers)
- Eli Lilly, the makers of Cymbalta, on (02) 9325 4622 or [www.lilly.com.au/ela/index.cfm](http://www.lilly.com.au/ela/index.cfm).

Please note that changing antidepressants requires careful medical supervision. Different antidepressants can interact with each other, and sometimes there needs to be a gap of 2–3 weeks after taking one medicine before starting another.

If you are considering changing antidepressants, you should do so only under medical supervision.

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**11.**  
**What does duloxetine cost?**

At the time of publication, the cost of a normal prescription through the PBS was:

- \$31.30 for people without a concession card
- \$5.00 for concession card holders.

The full cost to the Australian Government of each duloxetine 60 mg prescription is \$49.99, which is slightly higher than most other antidepressants. If you are prescribed duloxetine through the PBS, you pay only the cost of a normal prescription, and the Australian Government pays the rest.

Each prescription lasts 28 days, and you can get up to 5 repeats of duloxetine 60 mg.

**Most medicines prescribed by your doctor are covered by the Pharmaceutical Benefits Scheme. This means that the Australian Government pays part of the cost of your medicine.**

**You will need to pay the full price if the medicine is not available on the Pharmaceutical Benefits Scheme, or is not available on the Pharmaceutical Benefits Scheme for your specific condition.**

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## 12. Other ways to help this condition

There are many ways to help deal with major depression. They can contribute towards easing the depression, and may help reduce the amount of medicine required.

They involve:

- sleep
- exercise
- healthy eating
- avoiding alcohol and other drugs
- counselling or other psychological treatments.

Sleep is very important. Poor sleep can be a sign of depression, and getting a decent night's rest can be part of the road to recovery. Sleep can improve with:

- getting to bed at about the same time each night
- getting up at about the same time each day
- avoiding caffeine after lunch
- having a good relaxing night-time routine, which may involve reading and relaxation before bed.

Exercise can help break the cycle. Many people who feel depressed also feel very tired. Regular exercise, even a 30 minute walk most days, can help people feel more energetic, and help improve sleep.

Healthy eating will not bring about an instant fix, but it is part of establishing the healthy lifestyle that will contribute towards a recovery from depression.

If you have depression, then drinking alcohol will probably make it worse. If you are more than a light drinker, you should not use duloxetine.

Some illicit drugs can cause serious side effects if used with duloxetine. Ask your GP, psychiatrist, pharmacist or psychologist for more information about the specific risks with particular drugs.

Many forms of counselling or psychological treatment are effective for people with depression. For people with mild depression, they can be effective on their own. For people with moderate to severe major depression, they are usually used in addition to medication, and may improve the effectiveness of antidepressants. Treatment may be available through Medicare.

There is one more important way to treat depression — electroconvulsive therapy, or ECT. ECT is a useful treatment for people with very severe depression, and is sometimes lifesaving. It has a poor reputation based on the way it was used some decades ago. But ECT is now recommended as an effective option for people with very severe depression who are at risk of dying from suicide or through not eating or drinking.

**For more information  
contact:**

**beyondblue on  
1300 22 4636 or at  
[www.beyondblue.org.au](http://www.beyondblue.org.au)**

**SANE helpline on  
1800 18 SANE (7263)  
or at [www.sane.org](http://www.sane.org).**

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### 13. How new medicines are tested and approved for use in Australia

Prescription medicines go through many tests and clinical trials before they can be prescribed in Australia. All medicines go through four types of tests to assess their effectiveness, side effects and safety:

- **laboratory tests** (not involving people)
- **phase 1** clinical trials, typically with 20–80 healthy volunteers, to test the safety and dosage in people with normal physical health
- **phase 2** clinical trials, typically with 100–500 volunteers with the condition, to test the effectiveness and safety
- **phase 3** clinical trials, typically with 1000–3000 volunteers with the condition, to confirm the medicine’s effectiveness and find out more about its side effects.

Sometimes, less common side effects do not become obvious until large numbers of people have used the medicine.

The Therapeutic Goods Administration (Australia’s regulatory agency for medicines) checks clinical trial results before it approves the registration of the medicine for use in Australia.

Medicines are made available on the Pharmaceutical Benefits Scheme if they are shown to be as good as or better than other available medicines for the same condition.

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#### *Why Medicine Update?*

*Medicine Update* lets you know about new medicines and new PBS listings. When medicines are new, less is known about their expected benefits and possible harms than for older medicines. It's important to understand what evidence is available about both benefits and harms. *Medicine Update* provides balanced information to help you decide if a medicine is right for you.

#### *Who wrote Medicine Update?*

National Prescribing Service Limited (NPS), an independent, non-profit, government-funded organisation, wrote this information in consultation with consumers and health professionals.

#### *Who is it for?*

*Medicine Update* is written for people who are thinking about a new medicine, or have had a medicine suggested or prescribed for them and want to find out more.

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Visit the NPS website to find out about our free activities and resources  
for consumers [www.nps.org.au/consumers](http://www.nps.org.au/consumers)



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This review was conducted by the National Prescribing Service Limited (NPS) in consultation with consumers and health professionals.