

WARNING



National Prescribing Service Limited

Medicine update

asking the right questions about new medicines

Lumiracoxib (Prexige) for osteoarthritis

WARNING

Since this issue of *Medicine Update* was published, Prexige (lumiracoxib) has been **urgently withdrawn by the Therapeutic Goods Administration** because of a small number of cases of serious liver side effects. Prexige is no longer available in Australia. If you take Prexige, stop taking it immediately and see your doctor to discuss an alternative to this drug and to arrange any tests you may need. If you cannot see your doctor, talk to your pharmacist, or ring the Therapeutic Goods Administration (TGA) info line on 1800 004 599, Novartis Pharmaceuticals on 1800 671 203, or NPS Medicines Line on 1300 888 763.

To find out more about the withdrawal of Prexige in Australia:

[NPS media release](#)

[TGA advice for health professionals](#)

[TGA media statement](#)

[TGA recall notice](#)

[Novartis media release](#)

get to know your medicines

Visit the NPS website to find out about our free activities and resources
for consumers www.nps.org.au/consumers

This independent review was conducted by NPS in consultation with consumers and health professionals.
NPS is an independent, non-profit organisation for quality use of medicines funded by the
Australian Government Department of Health and Ageing.

Medicine update

asking the right questions about new medicines

Lumiracoxib (Prexige) for osteoarthritis

When you are thinking about a new medicine, follow the steps below to help you decide if it's right for you.

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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) for this medicine (available from your doctor or pharmacist, the consumer section at www.nps.org.au, or from the manufacturer).

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1.
**how to compare
new medicines —
risks and benefits**

When you are considering a new medicine it is important to find out how it compares with other treatments. To do this you need to weigh up the expected benefits and the possible risks of the new medicine, compared with other available medicines or treatments.

Sometimes new medicines have benefits like:

- greater effectiveness
- less serious side effects
- lower cost
- greater convenience.

The risks of new medicines can include:

- more serious side effects
- side effects which are more likely to affect you.

**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**

2.
**what this
medicine is**

Lumiracoxib (pronounced 'loo – MEE – rah – cox – ib')

Brand name: 'Prexige'

Active ingredient: lumiracoxib

Lumiracoxib is a type of medicine called an NSAID (pronounced 'en-sed'). 'NSAID' stands for 'non-steroidal anti-inflammatory drug'. NSAIDs are also known as 'anti-inflammatories'.

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

3.
**what this
medicine treats**

Lumiracoxib reduces pain and inflammation.

It is available under the Pharmaceutical Benefits Scheme (PBS) to treat osteoarthritis.

4.
**other medicines
available for
this condition**

If you are thinking about using an NSAID (non-steroidal anti-inflammatory drug) for your osteoarthritis for the first time, or you are already taking an NSAID, then lumiracoxib is one of several options.

Other NSAIDs available in Australia include:

- ibuprofen – brand names: 'Nurofen', 'Brufen' (plus others)
- naproxen – brand names: 'Naprosyn', 'Naprogesic'
- diclofenac – brand names: 'Voltaren', 'Diclohexal' (plus others)
- celecoxib – brand name: 'Celebrex'
- meloxicam – brand names: 'Mobic' and 'Movalis'.

These other NSAIDs also reduce pain and inflammation and are used to relieve joint and muscle pain from arthritis, backache and sprains. Some are used to treat headaches, period pain and minor injuries.

This review only compares lumiracoxib with other NSAIDs. Other medicines that are used for osteoarthritis include paracetamol and glucosamine – these may be recommended instead of, or as well as, NSAIDs.

**Talk with your doctor
about all of the
treatment options
for osteoarthritis.**

5.
**how well it works
compared with
other medicines**

Lumiracoxib has been compared in clinical trials with three other NSAIDs — diclofenac, celecoxib and ibuprofen — for osteoarthritis. The trials compared the pain and stiffness experienced by people taking lumiracoxib with that experienced by people taking the other NSAIDs. They also looked at whether lumiracoxib improved mobility.

The results found that lumiracoxib is no better or worse at reducing pain and stiffness, or improving mobility in people with osteoarthritis than these other NSAIDs.

This research suggests that lumiracoxib does not seem to be any more effective than other NSAIDs. However, you may find that one NSAID works better for you than other NSAIDs.

6.
**important side
effects to consider**

All medicines can have side effects. Sometimes the side effects are serious but most of the time they are not.

The serious side effects to consider when deciding whether to use lumiracoxib – or any other NSAID – are heart and stomach problems.

- Heart problems include heart attacks and strokes.
- Stomach problems can range from nausea or heartburn to stomach ulcers and serious stomach bleeding. More serious side effects, such as stomach bleeding, may need treatment in hospital and, in rare cases, can be fatal.

For a complete list of possible side effects, see the consumer medicine information (CMI) for lumiracoxib (see section 11 for details).

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

7.
**how these
side effects
compare with
other medicines**

HEART AND CIRCULATION PROBLEMS

People taking NSAIDs long-term appear to have a higher risk of heart attack and stroke than people who do not use NSAIDs. The number of people who will experience a heart attack with NSAIDs in the general population is very small.

However if you already have a high risk of heart or circulation problems, you should avoid using any NSAID — including lumiracoxib — if possible. Using an NSAID may increase your risk of heart and circulation problems further.

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7.

how these side effects compare with other medicines

Factors that may put you at risk of heart and circulation problems

You may have a higher risk of heart and circulation problems if you:

- have suffered a heart attack or stroke
- have blocked blood vessels in your legs or arms (peripheral vascular disease)
- have heart disease (coronary artery disease)
- have diabetes
- have kidney disease
- have high blood cholesterol levels
- have high blood pressure
- are a smoker, or have been a smoker
- are overweight or obese.

If you think any of these risk factors apply to you, you should discuss this information with your doctor.

STOMACH PROBLEMS

All NSAIDs, including lumiracoxib, can cause serious stomach problems. However, some NSAIDs are more likely to cause stomach problems than others.

For most people, the risk of serious stomach problems is the same whether they take lumiracoxib or another NSAID.

However, if you have a high risk of developing serious stomach problems with an NSAID, you should avoid using any NSAID— including lumiracoxib — if possible. If this is not possible, choose an NSAID that is less likely to cause stomach problems.

- if you have a high risk of developing stomach problems, lumiracoxib may be safer for you than naproxen or ibuprofen
 - you have a 12 in 1000 chance of developing a serious stomach problem if you take lumiracoxib for a year, compared to a 44 in 1000 chance with ibuprofen or naproxen

but if you are taking aspirin as well as lumiracoxib, the risk of serious stomach problems is the same as with ibuprofen or naproxen, because aspirin can also cause serious stomach problems.

- if you have a low risk of developing stomach problems it makes very little difference whether you take lumiracoxib, naproxen or ibuprofen
 - you have a 3 in 1000 chance of developing a serious stomach problem if you take lumiracoxib for a year, compared to an 11 in 1000 chance with ibuprofen or naproxen.

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Your doctor can assess your individual risk of getting heart and circulation problems and whether this prevents you from taking an NSAID.

Your doctor can assess your individual risk of developing stomach problems and whether this prevents you from taking an NSAID.

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7.

how these side effects compare with other medicines

Factors that may put you at risk of stomach problems

You may be at high risk of developing serious stomach problems with NSAIDs if you:

- are over 65 years old
- have suffered from a stomach ulcer
- take medicines such as oral corticosteroids or warfarin
- take higher doses of NSAIDs
- take NSAIDs for a long time (a year or more)
- have a serious illness such as heart disease, kidney or liver conditions, diabetes, or high blood pressure.

Having one of these factors can increase the risk of a serious stomach problem by two to four times.

If you think any of these risk factors apply to you, you should discuss this information with your doctor.

8.

how to reduce your risk of side effects

Use NSAIDs only when you need them, rather than every day, to reduce your risk of side effects.

Use the lowest dose that controls your pain, and talk to your doctor about other ways to manage your pain. For example, you may be able to manage your pain with regular doses of paracetamol, and only use an NSAID for extra pain relief when needed — such as when carrying out activities that usually increase your pain, e.g. exercise.

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

9.

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 for 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.

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

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

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

10.
who can
be prescribed
this medicine
on the PBS

Lumiracoxib became available on the Pharmaceutical Benefit Scheme (PBS) from 1 August 2006 (200 mg dose only).

This medicine can only be prescribed on the PBS for people with osteoarthritis.

If you have osteoarthritis and are eligible for the PBS, the cost you will pay is the 'PBS co-payment', set by the Australian government. In January 2007, the co-payment was

- \$30.70 for people without a concession card
- \$4.90 for concession card holders.

The cost to the government for each lumiracoxib prescription is \$29.91, however people without a concession card still pay \$30.70 because of pharmacy fees.

Lumiracoxib has also been shown to relieve period pain and pain caused by joint or dental surgery, however it is not available on the PBS for these uses. Speak to your doctor if you have any of these conditions and believe lumiracoxib may be suitable for you.

Most medicines prescribed by your doctor are covered by the PBS. 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 PBS, or is not available on the PBS for your specific condition.

11.
what else
you should
know about
this medicine

READ THE CONSUMER MEDICINE INFORMATION (CMI) LEAFLET

Before you start taking a new medicine, you should read the Consumer Medicine Information (CMI). The CMI will tell you:

- who should not take the medicine
- which medicines should not be taken at the same time (drug interactions)
- how to take the medicine
- a list of most possible side effects
- a list of all the ingredients.

You can get the CMI for lumiracoxib from:

- your doctor or pharmacist
- www.nps.org.au/consumers (click on 'Consumer Medicine Information' in the Quicklinks column on the left of the screen)
- Novartis Pharmaceuticals, the makers of lumiracoxib – phone 1800 671 203 (free call within Australia).

CMIs are available for most prescription medicines.

12. other ways to help this condition

Even if you are taking medicines there are other things you can do to help your osteoarthritis.

It is important to stay active if you have osteoarthritis. Regular exercise will help to

- relieve the pain in your joints
- maintain or improve the range of movement in your joints
- improve the strength of your muscles, which will make your joints more stable
- maintain a healthy body weight, which will reduce the load on your joints
- maintain general body fitness and sense of well-being.

You may find that medicines do not relieve pain completely. There are other things you can do to help relieve pain

- heat treatments, such as a heat pack or a warm bath, may help to relieve joint pain
 - cold packs may help to reduce swelling and pain
 - relaxation techniques, such as meditation or deep breathing, may help to relieve muscle tension and pain
 - focusing your attention on something you enjoy (such as listening to music, exercising or reading) may help to distract you from the pain.
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Speak to your doctor about what exercise program or treatment might be suitable for you.

To find out more about 'osteoarthritis' call Arthritis Australia on 1800 011 041 (free call in Australia), or visit arthritisaustralia.com.au

Date published: April 2007

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