

**What you should know about
FLEXIN[®]-25 CONTINUS[®] tablets,
FLEXIN[®]-50 CONTINUS[®] tablets and
FLEXIN[®]-75 CONTINUS[®] tablets**
Indometacin PhEur

Please read this leaflet before you start taking your tablets.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Keep this leaflet in a safe place - you may want to read it again.

What is in the tablets?

The tablets contain 25 mg, 50 mg, or 75 mg of the active ingredient indometacin. Indometacin belongs to a group of medicines called anti-inflammatory analgesics (painkillers that reduce swelling).

The tablets also contain the following inactive ingredients:

- * Lactose
- * Hydroxyethylcellulose
- * Cetostearyl alcohol
- * Magnesium stearate
- * Talc
- * Purified water
- * Macrogol
- * Hypromellose (75 mg tablet)

The tablets also have the colourants shown below:

25 mg tablet - titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110) and brilliant blue (E133).

50 mg tablet - iron oxide (E172) and erythrosine (E127).

75 mg tablet - quinoline yellow (E104) and titanium dioxide (E171).

There are 28 tablets (25 mg, 50 mg and 75 mg) or 56 tablets (25 mg) in each container.

The tablets are made by Bard Pharmaceuticals Limited for the marketing authorisation holder Napp Pharmaceuticals Ltd, both at the Cambridge Science Park, Milton Road, Cambridge, CB4 0GW, UK.

What are the tablets for?

The tablets are used to reduce swelling and relieve pain. They can be used for arthritis, gout, other joint disorders and painful periods. If you would like to know more about arthritis, read the section at the end of the leaflet.

Who can take the tablets?

Adults and the elderly can take the tablets. Children should not take the tablets. Before taking the tablets, please tell your doctor or pharmacist if:

- * you are pregnant or breast feeding,
- * you have a stomach ulcer or have had a stomach ulcer in the past,
- * you are allergic or sensitive to indometacin or aspirin, or any of the other tablet ingredients,
- * you are taking other anti-inflammatory painkillers,
- * you are taking digoxin (a medicine for heart conditions),
- * you are taking cyclosporin (a medicine for rheumatoid arthritis, dermatitis, psoriasis, or for transplant patients),
- * you are taking mifepristone (a drug used to induce an abortion), or have taken mifepristone in the last two weeks,
- * you are taking quinolone antibiotics (medicines that kill bacteria),
- * you have epilepsy or Parkinson's disease,
- * you have asthma,
- * you have liver problems,
- * you have kidney problems,
- * you have heart problems,
- * you have an infection,
- * you have any type of mental illness,
- * you have a blood clotting disorder,
- * you have hepatitis (swelling of the liver).

Also tell your doctor or pharmacist if you are taking:

- * aspirin,
- * diflunisal (another 'painkiller'),
- * probenecid (a medicine for gout),
- * beta-blockers or diuretics (medicines to lower blood pressure),
- * lithium (a medicine for depression),
- * anti-coagulants (medicines to stop your blood becoming too thick),
- * methotrexate (a medicine for psoriasis and cancer),
- * corticosteroids (medicines used to treat many common conditions including asthma, arthritis, and eczema).

Patients taking these tablets for long periods for rheumatoid arthritis, should have their eyes checked regularly.

Only take the tablets if they have been prescribed for you. Never give them to others, even if their symptoms are the same as yours.

Don't drive or operate machinery if the tablets make you feel dizzy.

How do I take my tablets?

The label on your medicine will tell you how many tablets to take and how often. If you are not sure, ask your doctor or pharmacist.

Always swallow your tablets whole with food or milk, or whilst taking an antacid (a medicine for ulcers, indigestion, or heartburn).

Don't crush or chew them.

The usual dose is 1 or 2 tablets every 12 hours. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock in the evening. Your doctor may prescribe a different dose. You may want to discuss this with your doctor.

What should I do if I forget to take my tablets?

If you forget to take your tablets, take your next dose as soon as you remember, unless it is almost time for your next dose. Then go on as before.

What should I do if someone accidentally swallows my tablets or if I take too many?

Call your doctor or local hospital straight away.

Will I have any problems?

Most people will not have any problems when taking the tablets. Problems that do occur are usually mild and wear off after a few days.

In a few people some of the following may occur: headache, dizziness, dyspepsia (heartburn), tinnitus (ringing in the ear), nausea (feeling sick), vomiting (being sick), stomach pain, diarrhoea (loose bowel motions), and ulcers. Some patients may suffer from an allergic reaction such as a rash or itching.

Occasionally there have been reports of high blood pressure, oedema (swelling caused by fluids), hair loss, eye problems, kidney problems, haematuria (blood when passing water), anorexia (loss of appetite), and bleeding disorders (such as bruises or dark tarry stools).

On rare occasions, a patient may have breathing problems, suffer from mental illness, or have convulsions (fits).

If these occur or you have any other problems, please tell your doctor.

How should I keep my tablets?

There is a 'use-by' date on the label. For example, EXP 8.2005 means that you should not use the tablets after the end of August 2005. After the 'use-by' date, you should return your tablets to a pharmacy.

Do not keep your tablets above 25°C (77°F). Keep them in a safe place where children cannot see or reach them.

Date this leaflet was written:

January 2001

What is arthritis?

Arthritis is a swelling of one or more of your joints. The joints can also become warm and painful. Arthritis may also affect your general health.

What can I do to help?

Your doctor or physiotherapist will be able to show you exercises that can help your arthritis.

However, if you would like more information about arthritis, you can contact:

Arthritis Care
18 Stephenson Way,
London NW1 2HD
Telephone: 0171 916 1500

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