

INDOCID capsule/ suppository

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using INDOCID?

INDOCID contains the active ingredient indometacin. INDOCID is used to relieve pain and reduce inflammation (swelling, redness and soreness) that may occur in the following conditions: different types of arthritis, muscle and bone injuries, swelling and pain after setting broken or dislocated bones, and menstrual cramps.

For more information, see Section [1. Why am I using INDOCID?](#) in the full CMI.

2. What should I know before I use INDOCID?

Do not use if you have ever had an allergic reaction to INDOCID or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use INDOCID?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INDOCID and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use INDOCID?

- Always use this medicine exactly as your doctor or pharmacist has told you.

More instructions can be found in Section [4. How do I use INDOCID?](#) in the full CMI.

5. What should I know while using INDOCID?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using INDOCID.• Tell your doctor straight away if you become pregnant while using INDOCID.• Tell your doctor straight away if you get an infection while using INDOCID.
Things you should not do	<ul style="list-style-type: none">• Do not use more than the recommended dose or stop using the medicine unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how INDOCID affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool (below 25°C), dry place away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Side effects include stomach upset, loss of appetite, constipation, diarrhoea, discomfort in the back passage(suppositories only), hearing disturbances, headache, dizziness, tiredness, change in mood.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

INDOCID capsule/ suppository

Active ingredient: *indometacin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using INDOCID. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INDOCID.**

Where to find information in this leaflet:

1. [Why am I using INDOCID?](#)
2. [What should I know before I use INDOCID?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use INDOCID?](#)
5. [What should I know while using INDOCID?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using INDOCID?

INDOCID contains the active ingredient **indometacin**. INDOCID belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or NSAID).

INDOCID is used to relieve pain and reduce inflammation (swelling, redness and soreness) that may occur in the following conditions:

- different types of arthritis including rheumatoid arthritis, osteoarthritis, gouty arthritis and ankylosing spondylitis
- muscle and bone injuries such as sprains, strains, low back pain (lumbago) and tendonitis, such as tennis elbow
- swelling and pain after setting broken or dislocated bones
- menstrual cramps (period pain).

Your doctor may have prescribed it for another reason.

There is no evidence that it is addictive.

2. What should I know before I use INDOCID?

Warnings

Do not use INDOCID if:

- you are allergic to indometacin, aspirin, other NSAID medicines or any of the ingredients listed at the end of this leaflet.
Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines.
Some symptoms of an allergic reaction may include:
 - asthma

- shortness of breath
- wheezing or troubled breathing
- swelling of the face, lips, tongue or other parts of the body
- fainting
- rash, itching or hives on the skin.

If you are allergic to aspirin or NSAID medicines and use INDOCID, the above symptoms may be severe.

Always check the ingredients to make sure you can use this medicine.

- you have an active peptic ulcer (i.e. stomach or duodenal ulcer) or have had peptic ulcers more than once before.
- you have severe heart failure.
- you have recently had heart bypass surgery.
- you have severe liver.
- you have had an inflamed rectum (back passage) or recent bleeding from the rectum. This only applies to INDOCID suppositories.
- you are pregnant, or intend to become pregnant.
- you are breast-feeding or intend to breast-feed.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Pregnancy and breastfeeding

Do not use INDOCID if you are pregnant or intend to become pregnant. The safety of this medicine during pregnancy has not been established.

Do not use INDOCID if you are breastfeeding or intend to breastfeed. The active ingredient indometacin passes into breast milk and there is a possibility that your baby may be affected.

Use in children

INDOCID should not be given to children under 2 years of age. The safety of this medicine in children under 2 years of age has not been established.

Use in the elderly

- Elderly patients may be more sensitive to the effects or side effects of this medicine.

Tell with your doctor if you:

- are allergic to any other medicines including aspirin, other NSAID medicines or any other substances such as foods, dyes or preservatives.
- have or have had any of the following medical conditions:
 - heartburn, indigestion, stomach ulcer or other stomach problems
 - bowel or intestinal problems such as ulcerative colitis

- kidney or liver disease
- high blood pressure or heart disease
- history of chest pain (angina), heart problems or stroke
- a tendency to bleed or other blood problems
- diabetes mellitus or sugar diabetes
- psychiatric problems
- seizures or fits (epilepsy)
- Parkinson's disease.
- currently have an infection.
INDOCID may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is less serious than it might be.
Signs of an infection include fever, pain, swelling or redness.

If you have not told your doctor about any of the above, tell them before you use any INDOCID.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with INDOCID and affect how it works. These include:

- aspirin, salicylates or other NSAID medicines (e.g. ibuprofen or diflunisal)
- anticoagulants such as warfarin, a medicine used to prevent blood clots
- cardiac glycosides or digoxin, a medicine used to treat heart failure
- lithium, a medicine used to treat severe mood swings
- probenecid, a medicine used to treat gout
- diuretics, also called fluid or water tablets
- some medicines used to treat high blood pressure in combination with a thiazide diuretic
- decongestants
- ciclosporin, a medicine used to suppress the immune system
- methotrexate, a medicine used to treat arthritis and some cancers
- corticosteroids, an anti-inflammatory medicine
- Mifepristone, a medicine used for medical abortion
- Quinolone antibiotics and vancomycin.

These medicines may be affected by INDOCID or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INDOCID.

4. How do I use INDOCID?

INDOCID CAPSULES

How much to take

- Your doctor will tell you how many capsules you need to take each day.
- The dose will depend on the condition being treated and your response to the treatment. Your initial dose will be maintained or adjusted until a satisfactory response is noted.

Tell your doctor of any changes in your condition, as you may require a change in the dose of INDOCID.

How to take INDOCID capsules

- Take the capsules straight after food or milk with a full glass of water.
- INDOCID may also be taken with antacid, if advised by your doctor or pharmacist.
This may help reduce the possibility of stomach and bowel problems.

INDOCID SUPPOSITORIES

How much to use

- Your doctor will tell you how many suppositories you need to use each day.

How to use INDOCID suppositories

If possible, go to the toilet and empty your bowels before using the suppository.

INDOCID suppositories work best if your bowel has been emptied.

Follow these steps to use a suppository:

1. Wash your hands thoroughly with soap and water.
2. Feel the suppository while it is still in the foil.
3. If it feels soft, keep in the foil, chill in the fridge or by holding it under cold water for a few minutes. **Do not remove the foil wrapper while you are chilling it.**
4. Put on a disposable glove, if desired (available from pharmacy)
5. Remove the entire foil wrapper from the suppository.
6. Moisten the suppository by dipping it briefly in cool water.
7. Lie on your side and raise your knee to your chest.
8. Push the suppository gently into your rectum (back passage).
9. Remain lying down for a few minutes so that the suppository dissolves.
10. Throw away used materials and wash your hands thoroughly.

Try not to go to the toilet and open your bowels for at least an hour after using the suppository.

The suppository takes about one hour to be completely absorbed and do its work.

If you are not sure how to use a suppository, ask your doctor or pharmacist.

How long to use it

Continue using this medicine for as long as your doctor tells you.

- Depending on your condition, you may need this medicine for a few days, a few weeks or for longer periods.
- As with other NSAID medicines, if you are using INDOCID for arthritis, it will not cure your condition but it should help to control pain, swelling and stiffness. If you have arthritis, INDOCID should be taken every day for as long as your doctor prescribes.
- For sprains and strains, INDOCID is usually only needed for a few days.
- For menstrual cramps, INDOCID should be taken at the start of bleeding or cramps and continued for as long as the cramps last.

If you forget to use INDOCID

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the capsule or use the suppository as soon as you remember, and then go back to using it as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much INDOCID

If you think that you have used too much INDOCID, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include nausea, vomiting, intense headache, dizziness, confusion, fatigue, numbness or fits.

5. What should I know while using INDOCID?

Things you should do

Tell your doctor straight away if you:

- become pregnant while using INDOCID.
- get an infection while using INDOCID.
INDOCID may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is less serious than it might be.
Signs of an infection include fever, pain, swelling or redness.

Tell any doctor, dentist or pharmacist who are treating you that you are using INDOCID, especially if you are being started on any new medicines

Things you should not do

- Do not use more than the recommended dose unless your doctor tells you to.
- Do not use INDOCID to treat any other complaints unless your doctor tells you to.
- Do not give INDOCID to anyone else, even if they have the same condition as you
- Do not stop using your medicine or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how INDOCID affects you.

As with other NSAID medicines, this medicine may cause dizziness or light-headedness in some people. If this occurs, do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Drinking alcohol

If you drink alcohol, the dizziness or light-headedness may be worse.

Things to be aware of

- INDOCID can increase blood pressure in some people, so your doctor will want to check your blood pressure from time to time.
- As blurred vision is a possible side effect of long term therapy with INDOCID, patients should visit their optometrist for regular eye checks.

Looking after your medicine

- Keep your capsules or suppositories in their original pack until it is time to use them.
- Suppository: Do not take it out of the foil until it is time to use them.
- Store below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

INDOCID helps most people with pain and inflammation, but it may have unwanted side effects in a few people. If you are over 65 years of age you may have an increased chance of getting side effects.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal-related <ul style="list-style-type: none">• stomach upset or pain including nausea (feeling sick), vomiting, heartburn, indigestion. Some of the stomach upsets, such as nausea and heartburn, may be reduced by taking the capsules with food or an antacid, if advised by your doctor or pharmacist. <ul style="list-style-type: none">• loss of appetite• constipation, diarrhoea• irritation or discomfort in the back passage (this happens only with the suppositories) Nervous system-related <ul style="list-style-type: none">• hearing disturbances• headache, dizziness, light-headedness may occur in the first few days of treatment. If this worries you or continues, contact your doctor.• tiredness• change in mood for example, depression	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Gastrointestinal-related <ul style="list-style-type: none">• severe pain or tenderness in the stomach Heart and blood-related	Tell your doctor immediately if you notice any of these serious side effects.

- fast or irregular heartbeats, also called palpitations
- signs of anaemia, such as tiredness, being short of breath, looking pale
- unusual weight gain, swelling of ankles or legs

Kidney and liver-related

- bleeding or bruising more easily than normal
- yellowing of the skin and eyes, also called jaundice
- dark coloured or cloudy urine or pain in the kidney region
- difficulty in passing water (urinating) or a sudden decrease in the amount of urine passed.

Other

- eye problems such as blurred vision or difficulty seeing
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers

Gastrointestinal-related

- vomiting blood or material that looks like coffee ground. This may occur at any time during use and without warning.
- Bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea. This may occur at any time during use and without warning

Allergic reaction-related

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives

Other

- severe dizziness, lightheadedness or fainting
- seizures or fits
- pain or tightness in the chest.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What INDOCID contains

CAPSULE

Active ingredient (main ingredient)	Indomethacin, 25 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Lactose monohydrate• lecithin• colloidal anhydrous silica• magnesium stearate• gelatin• titanium dioxide• iron oxide yellow CI77492• opacode monogramming ink S-1-17823 black

INDOCID capsules do not contain sucrose, gluten, tartrazine or any other azo dyes.

SUPPOSITORY

Active ingredient (main ingredient)	Indomethacin, 100 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• butylated hydroxyanisole• butylated hydroxytoluene• edetic acid• glycerol• macrogol 3350• macrogol 8000• purified water

INDOCID suppositories do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What INDOCID looks like

INDOCID capsule is opaque ivory marked with '25' in black on either the body or cap. A pack contains 50 capsules (AUST R 76021).

INDOCID suppository is white opaque torpedo-shaped with a yellow tinge. Each is wrapped in foil. A pack contains 20 suppositories (AUST R 10480).

Who distributes INDOCID

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia
www.aspenpharmacare.com.au

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