

INDOCID®

tablet/suppository

indomethacin

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about INDOCID. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking INDOCID against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What INDOCID is used for

INDOCID contains indomethacin as the active ingredient. It 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).

Ask your doctor if you have any questions about why INDOCID has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

There is no evidence that it is addictive.

Before you use it

When you must not use it

Do not use INDOCID if you have ever had an allergic reaction to:

- indomethacin
- any of the ingredients listed at the end of this leaflet
- aspirin or any other NSAID medicines.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines.

Symptoms of an allergic reaction to these medicines may include asthma, shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any 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.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

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 it if you are breast-feeding or intend to breast-feed.

It is not recommended for use while breastfeeding as it is found in breast milk.

Do not use INDOCID if:

- you have an active peptic ulcer (i.e. stomach or duodenal ulcer) or have had peptic ulcers more than once before
- you have recently had heart bypass surgery
- you have had an inflamed rectum (back passage) or recent bleeding from the rectum.

This only applies to INDOCID suppositories.

Do not use INDOCID if:

- **the packaging is torn or shows signs of tampering**
- **the expiry date (EXP) printed on the pack has passed.**

If you use this medicine after the expiry date has passed, it may not work as well.

Do not use this medicine to treat any other complaints unless your doctor has instructed you to do so.

Do not give INDOCID to children under 2 years of age.

The safety of this medicine in children under 2 years of age has not been established.

Before you start to use it

Tell 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.

Tell your doctor if you 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.

Tell your doctor if you 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.

Taking other medicines

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

Some medicines and INDOCID may interfere with each other. These include:

- aspirin, salicylates or other NSAID medicines (e.g. ibuprofen or diflunisal)
- anticoagulants such as warfarin, a medicine used to prevent blood clots
- 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
- cyclosporin, a medicine used to suppress the immune system
- methotrexate, a medicine used to treat arthritis and some cancers.

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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using INDOCID.

Use in elderly

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

How to use it

INDOCID CAPSULES

How many capsules 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 the capsules

Take the capsules straight after food or milk with a full glass of water.

It may also be taken with an 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 the suppositories

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

They work best if your bowels are empty.

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 it in the fridge or by holding it under cold water for a few minutes.
4. Put on a disposable glove, if desired (available from a 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 it

If it is almost time for your next dose, skip the dose you missed and take or use 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.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much INDOCID or have swallowed a suppository. Do this even if there are no signs of discomfort or poisoning.

If you take too much INDOCID, you may suffer nausea, vomiting, intense headache, dizziness, confusion, fatigue, numbness or fits.

While you are using it

Things you must do

Tell your doctor immediately if you become pregnant while using INDOCID.

Tell any other doctors, dentists and pharmacists who are treating you that you are using INDOCID, especially if you are being started on any new medicines.

Tell your doctor if you 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.

Things you must not do

Do not give INDOCID to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery 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.

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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using INDOCID.

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. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following common side effects and they worry you:

- 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.

- loss of appetite
- constipation, diarrhoea
- 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
- irritation or discomfort in the back passage (this happens only with the suppositories).

Tell your doctor immediately if you notice any of the following:

- severe pain or tenderness in the stomach
- eye problems such as blurred vision or difficulty seeing
- fast or irregular heartbeats, also called palpitations
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- signs of anaemia, such as tiredness, being short of breath, looking pale
- yellowing of the skin and eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- 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.

These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop using INDOCID and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- vomiting blood or material that looks like coffee grounds. 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
- 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
- severe dizziness, lightheadedness or fainting
- seizures or fits
- pain or tightness in the chest.

These are serious side effects that need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other side effects while using INDOCID.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using INDOCID

Storage

Keep your capsules and suppositories in their original pack until it is time to take them.

Do not take the suppositories out of the foil until it is time to use them.

If you take the capsules and suppositories out of the box or blister they may not keep as well.

Keep this medicine in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using INDOCID or it has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

INDOCID capsules:

Yellow capsule marked with '25' in black on either the body or cap.

A pack contains 50 capsules.

INDOCID suppositories:

White opaque torpedo-shaped suppository with a yellow tinge. Each is wrapped in foil.

A pack contains 20 suppositories.

Ingredients

INDOCID capsules:

Each INDOCID capsule contains 25 mg of indomethacin as the active ingredient.

It also contains the inactive ingredients:

- lactose
- lecithin
- silica-colloidal anhydrous
- magnesium stearate
- gelatin
- titanium dioxide
- iron oxide yellow CI77492

- opacode monogramming ink
S-1-27794 black or TekPrint
SW-8008 black ink.

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

INDOCID suppositories:

Each INDOCID suppository contains 100 mg of indomethacin as the active ingredient.

It also contains the inactive ingredients:

- butylated hydroxyanisole
- butylated hydroxytoluene
- edetic acid
- glycerol
- macrogol 3350
- macrogol 8000.

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

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065

Australian Register Numbers for
INDOCID products are:

25 mg capsule: AUST R 76021

100 mg suppository: AUST R 10480

This leaflet was prepared in August
2010.