

INDOCID(R)

Indomethacin

Consumer Medicine Information

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 relieves pain and reduces 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)

INDOCID belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

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

INDOCID is not addictive.

Before you use INDOCID

When you must not use it

Do not use INDOCID if:

- * **you have an allergy to INDOCID or any of the ingredients listed at the end of this leaflet**
- * **you have an allergy to aspirin or any other NSAID medicine**

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

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

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

Do not use INDOCID if:

- 1. you are pregnant, or intend to become pregnant**

INDOCID may affect your developing baby if you take it during pregnancy.

- 2. you are breast-feeding or intend to breast-feed**

INDOCID passes into breast milk and therefore may harm the baby.

- 3. you have an active peptic ulcer (ie. stomach or duodenal ulcer), or have had peptic ulcers more than once before**

- 4. you have recently had heart bypass surgery**

- 5. you have had an inflamed rectum (back passage) or recent bleeding from the rectum**

This applies to the suppositories only.

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.

If you are not sure whether you should start using INDOCID, talk to your doctor.

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

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

Before you start to use it

Tell your doctor if:

1. you have any allergies to:

- * any other medicines including aspirin or other NSAID medicines
- * any other substances, such as foods, preservatives or dyes

2. you have or have had any medical conditions, especially the following:

- * 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

3. you currently have an infection

If you use INDOCID while you have an infection, the capsules or suppositories may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is less serious than it might be.

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 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
- * 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
 - * 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 will advise you.

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

How to use INDOCID

How to take the capsules

Take INDOCID only when prescribed by your doctor.

Your doctor will tell you how many capsules you need to take each day. This depends on your condition. The dose usually ranges between 50 mg and 200 mg per day, given in divided doses. Your doctor may start you on a low dose of INDOCID and then increase the dose if necessary, depending on your response.

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

The dose for menstrual cramps (period pain) is usually one 25 mg capsule every eight hours, starting with the onset of bleeding or cramps.

You should only need to take INDOCID for a few days while you are having your period.

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

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to use the suppositories

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

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

Suppositories 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. Do not remove the foil wrapper while you are chilling it.
4. Put on a disposable glove, if desired (available from a pharmacy).
5. Remove all of the 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 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

Do not use INDOCID for longer than your doctor says.

Depending on your condition, you may need INDOCID 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 are not sure how long to use INDOCID, talk to your doctor.

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 a Poisons Information Centre

(telephone 13 11 26), 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, headache, dizziness, confusion, fatigue, numbness or fits.

While you are using INDOCID

Things you must do

If you become pregnant while using INDOCID, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using INDOCID.

Tell all of the doctors, dentists, and pharmacists that are treating you that you are using INDOCID.

If you get an infection while using INDOCID, tell your doctor.

INDOCID may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is not serious. 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, INDOCID may cause dizziness or light-headedness in some people. Make sure you know how you react to INDOCID before you drive a car,

operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

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

INDOCID can increase blood pressure in some people, so your doctor will want to check your blood pressure from time to time.

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 and they worry you:

- * stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion
- * loss of appetite
- * constipation, diarrhoea, pain in the stomach
- * headache, dizziness, light-headedness
- * tiredness, spinning sensation (vertigo)
- * change in mood for example, depression
- * irritation or discomfort in the back passage (this happens only with the suppositories)

These are the more common side effects of INDOCID.

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. Headache may occur in the first few days of treatment. If this worries you or continues, contact your doctor.

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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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 well.

Keep your INDOCID in a cool dry place where the temperature stays below 30 degrees C for the capsules, and below 25 degrees C for the suppositories.

Do not store INDOCID 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 the capsules or suppositories have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

INDOCID comes in capsules and suppositories.

- * Capsule - is ivory coloured with '25' and 'MSD' marked on the capsule. A pack contains 50 capsules.
- * Suppository - is yellowish-white and torpedo-shaped. Each is wrapped in foil. A pack contains 20 suppositories.

Ingredients

Capsules

- * Indomethacin 25 mg per capsule (active ingredient)
- * Lactose
- * Lecithin
- * Silica-colloidal anhydrous
- * Magnesium stearate
- * Gelatin
- * Titanium dioxide
- * Iron oxide yellow CI77492
- * Opacode S-1-8100 HV Black 1007 printing ink

Suppositories

- * Indomethacin 100 mg per suppository (active ingredient)
- * Butylated hydroxyanisole
- * Butylated hydroxytoluene
- * Edetic acid
- * Glycerol
- * Macrogol 3350
- * Macrogol 8000

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

Supplier

INDOCID is supplied in Australia
by:

Merck Sharp & Dohme (Australia)
Pty Limited
A.B.N. 14 000 173 508
54-68 Ferndell Street
South Granville NSW 2142

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