

ARTHREXIN™

Consumer Medicine Information (CMI) summary

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

1. Why am I taking ARTHREXIN?

ARTHREXIN contains the active ingredient indometacin. ARTHREXIN 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, gout, swelling and pain after setting broken or dislocated bones, and menstrual cramps.

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

2. What should I know before I take ARTHREXIN?

Do not take if you have ever had an allergic reaction to indometacin 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 take ARTHREXIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARTHREXIN 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 take ARTHREXIN?

- Your doctor will tell you how many capsules you need to take each day.
- Your dose will depend on the condition being treated and your response to the treatment.

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

5. What should I know while taking ARTHREXIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are taking ARTHREXIN.</p> <ul style="list-style-type: none"> • Tell your doctor straight away if you become pregnant while taking ARTHREXIN. • Tell your doctor straight away if you get an infection while taking ARTHREXIN.
Things you should not do	<ul style="list-style-type: none"> • Do not take more than the recommended dose or stop using the medicine unless your doctor tells you. • 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 ARTHREXIN affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Store it in a cool dry place where the temperature stays below 30°C away

from moisture, heat or sunlight.

- Keep your capsules in their original container until it is time to take them.

For more information, see Section [5. What should I know while taking ARTHREXIN?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include stomach upset, loss of appetite, constipation, diarrhoea, hearing disturbances, headache, dizziness, tiredness, change in mood. **Serious side effects** include severe stomach pain or tenderness, fast or irregular heart beats, signs of anaemia, unusual weight gain, swelling of ankles or legs, bleeding or bruising more easily than normal, yellowing of skin or eyes, dark coloured or cloudy urine, difficulty urinating, eye problems, signs of frequent or worrying infections, vomiting blood, bleeding from the back passage, black sticky bowel motions, severe dizziness, seizures, tightness in chest, or signs of an allergic reaction such as swelling of the face, lips or tongue, wheezing, shortness of breath, sudden or severe itching.

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.

ARTHREXIN™

Active ingredient(s): *indometacin*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking ARTHREXIN?

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

ARTHREXIN is taken 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, ankylosing spondylitis and degenerative joint disease of the hip
- gout
- muscle and bone injuries such as sprains, strains, low back pain (lumbago) and tendonitis, such as tennis elbow
- pain and swelling after setting broken or dislocated bones
- menstrual cramps (period pain).

Although ARTHREXIN can relieve the symptoms of pain and inflammation, it will not cure your condition.

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

Your doctor may have prescribed it for another reason.

There is no evidence that it is addictive.

2. What should I know before I take ARTHREXIN?

Warnings

Do not take ARTHREXIN if:

- you are allergic to any medicine containing 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 other NSAID medicines. Some of the symptoms of an allergic reaction may include:

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

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

If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.

Always check the ingredients to make sure you can take 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 failure.
- you are vomiting blood or material that looks like coffee grounds.
- you are bleeding from the back passage, have black sticky bowel motions or bloody diarrhoea.

- you experience asthma attacks, hives or rash or itching of the nose, throat or eyes with aspirin or other NSAIDS.
- you are pregnant or intend to become pregnant.
- you are breastfeeding or intend to breastfeed.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Pregnancy and breastfeeding

Do not take ARTHREXIN if you are pregnant or intend to become pregnant.

The safety of this medicine during pregnancy has not been established. ARTHREXIN may affect your developing baby if you take it during pregnancy. If it is necessary for you to take ARTHREXIN, your doctor will discuss the risks and benefits of taking it during pregnancy.

Women considering pregnancy should not use ARTHREXIN unless advised to by their doctor. ARTHREXIN may have a reversible inhibitory effect on fertility.

Do not take ARTHREXIN if you are breastfeeding or intend to breastfeed.

The active ingredient in ARTHREXIN passes into breast milk and there is a possibility that your baby may be affected.

Use in children

ARTHREXIN 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 elderly

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

Tell your doctor if you:

- are allergic to any other medicines, including aspirin and other NSAID medicines, 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
 - history of swelling in the feet or ankles
 - a tendency to bleed or other blood problems
 - diabetes mellitus or sugar diabetes

- psychiatric problems
- seizures or fits (epilepsy)
- Parkinson's disease
- asthma
- eye disease.
- currently have an infection.

ARTHREXIN 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.

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 start taking ARTHREXIN.

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 ARTHREXIN 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 such as digoxin, a medicine used to treat heart failure or irregular heart beats
- lithium, a medicine used to treat mood swings and some types of depression
- probenecid, a medicine used to treat gout
- diuretics, also called fluid or water tablets
- some medicines used to treat high blood pressure or heart conditions, including ACE inhibitors or betablockers or medicines used in combination with a thiazide diuretic
- decongestants
- ciclosporin, a medicine used to prevent organ transplant rejection or suppress the immune system
- methotrexate, a medicine used to treat arthritis and certain types of cancers
- corticosteroids, an anti-inflammatory medicine
- mifepristone, a medicine used for medical abortion
- quinolone antibiotics and vancomycin
- gold preparations.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARTHREXIN.

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

4. How do I take ARTHREXIN?

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

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.
- The dose varies from patient to patient. The usual dose is between 50 mg and 200 mg per day, given in divided doses.
- Elderly patients may need smaller doses.
- The dose for menstrual cramps (period pain) is usually one 25 mg capsule every eight hours, starting with the onset of bleeding or cramps.

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

How to take it

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

When to take it

- Take ARTHREXIN with or immediately after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

- 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 ARTHREXIN for arthritis, it will not cure your condition but it should help to control pain, swelling and stiffness. If you have arthritis, ARTHREXIN should be taken every day for as long as your doctor prescribes.
- For sprains and strains, ARTHREXIN is usually only needed for a few days.
- For gout, ARTHREXIN can be stopped when all symptoms subside.

- For menstrual cramps, ARTHREXIN should be taken at the start of bleeding or cramps and continued for as long as the cramps last.

If you forget to take ARTHREXIN

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 as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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 take too much ARTHREXIN

If you think that you or anyone else has taken too much ARTHREXIN, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking ARTHREXIN?

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ARTHREXIN.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

ARTHREXIN may cause prolonged bleeding and may need to be stopped before surgery.

- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
- Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor straight away if you:

- become pregnant while using ARTHREXIN.

- you get an infection while taking ARTHREXIN.
ARTHREXIN 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 should not do

- Do not take more than the recommended dose unless your doctor tells you to.
- Do not take ARTHREXIN to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking 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 ARTHREXIN affects you.

As with other NSAID medicines, this medicine may cause dizziness or light-headedness in some people. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

If you drink alcohol, the 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

- ARTHREXIN 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 ARTHREXIN, patients should visit their optometrist for regular eye checks.

Looking after your medicine

- Keep your capsules in their original pack until it is time to take them.
- Store below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Heat or dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

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

ARTHREXIN helps most people with pain or inflammation, but it may have unwanted side effects in a few people. If you are over 65 years of age, have liver or kidney problems or are diabetic, 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.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> ● stomach upset or pain including nausea (feeling sick), vomiting, cramps, loss of appetite ● heartburn or indigestion (possible symptoms of an ulcer in the tube that carries food from the throat to the stomach) <ul style="list-style-type: none"> ○ Some of the stomach upset, such as nausea and heartburn, may be reduced by taking the capsules with food or an antacid, if advised by your doctor or pharmacist. ● constipation, diarrhoea <p>Nervous system-related:</p> <ul style="list-style-type: none"> ● hearing disturbances such as buzzing or ringing in the ears ● headache, dizziness, light-headedness may occur in the first few 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are the more common side effects of ARTHREXIN.</p>

Less serious side effects	What to do
<p>days of treatment. If this worries you or continues, contact your doctor</p> <ul style="list-style-type: none"> ● tiredness ● change in mood such as depression, anxiety or irritability 	

Serious side effects

Serious side effects	What to do
<p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> ● severe pain or tenderness in the stomach <p>Heart and blood-related:</p> <ul style="list-style-type: none"> ● fast or irregular heartbeats, also called palpitations ● signs of anaemia, such as tiredness, being short of breath, looking pale ● unusual weight gain or swelling of ankles or legs <p>Kidney or liver-related:</p>	<p>Tell your doctor immediately if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 <p>Nervous system-related:</p> <ul style="list-style-type: none"> ● eye problems such as blurred vision or difficulty seeing ● drowsiness, disorientation, forgetfulness ● shakiness, sleeplessness, nightmares ● tingling or numbness of the hands or feet <p>Other:</p> <ul style="list-style-type: none"> ● signs of frequent or worrying infections such as fever, severe chills, 	

Serious side effects	What to do
sore throat or mouth ulcers	

Very serious side effects

Very serious side effects	What to do
<p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> • 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 <p>Allergic reaction-related:</p> <ul style="list-style-type: none"> • swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing • sudden or severe itching, skin rash or 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>This list includes very serious but rare side effects</p>

Very serious side effects	What to do
<p>hives, blistering or peeling of the skin</p> <ul style="list-style-type: none"> ● asthma, wheezing, shortness of breath <p>Other:</p> <ul style="list-style-type: none"> ● severe dizziness, light-headedness or fainting ● seizures or fits ● pain or tightness in the chest 	

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 ARTHREXIN contains

Active ingredient (main ingredient)	Indometacin, 25 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Lactose monohydrate• Sodium starch glycollate• Sodium lauryl sulfate• Magnesium stearate• Empty Hard Gelatin Capsules Bovine Size 3 White-Opaque/White-Opaque G3ICSRA0399 (ARTG PI No: 140186)• Opacode Black A-10259 (ARTG PI No: 1659)
Potential allergens	Sulfites and sugars as lactose

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

What ARTHREXIN looks like

ARTHREXIN capsules are white opaque hard gelatin capsules, marked "IN-25" on both body and cap. Each carton contains 50 capsules (AUST R 353404).

Who distributes ARTHREXIN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in June 2024.

ARTHREXIN™ is a Viatris company trade mark

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