

ARTHREXIN

indometacin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ARTHREXIN. 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 ARTHREXIN 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 ARTHREXIN is used for

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

ARTHREXIN 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, 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.

This medicine is not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 2 years

Before you take ARTHREXIN

When you must not take it

Do not take ARTHREXIN if you have an allergy to:

- any medicine containing indometacin
- aspirin or any other NSAID medicines
- 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.

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

Some of the symptoms of an allergic reaction may include:

- 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.

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

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

The safety of this medicine during pregnancy has not been established.

Do not breastfeed if you are taking this medicine.

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

Do not take ARTHREXIN if:

- you have an active peptic ulcer (i.e. a 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 experience asthma attacks, hives or rash or itching of the nose, throat or eyes with aspirin or other NSAIDs
- 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

Do not take this medicine after the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, including aspirin and other NSAID medicines, foods, dyes or preservatives.

Tell your doctor if you have, or have had, any of the following medical conditions:

- stomach ulcers or other stomach problems
- heartburn or indigestion
- bowel or intestinal problems such as ulcerative colitis
- kidney or liver disease
- diabetes
- 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
- psychiatric problems

- seizures or fits (epilepsy)
- Parkinson's disease
- asthma
- eye disease

Tell your doctor if you 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.

Taking other medicines

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

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

- aspirin, salicylates or other NSAID medicines (e.g. ibuprofen)

- anticoagulants such as warfarin, a medicine used to prevent blood clots
- 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 known as 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

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.

Use in the elderly

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

How to 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 box/bottle, 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.

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

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

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 it

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 it 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 what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

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

You may need urgent medical attention.

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

While you are 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 become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if 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.

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.

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.

Things you must not do

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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

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

This medicine helps most people with pain or inflammation, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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.

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

You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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)

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
- hearing disturbances such as buzzing or ringing in the ears
- 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 such as depression, anxiety or irritability

These are the more common side effects of ARTHREXIN.

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 or 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
- drowsiness, disorientation, forgetfulness
- shakiness, sleeplessness, nightmares
- tingling or numbness of the hands or feet

If any of the following happen, 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
- sudden or severe itching, skin rash or hives on the skin
- asthma, wheezing, shortness of breath

- severe dizziness, light-headedness or fainting
- seizures or fits
- pain or tightness in the chest

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

Other side effects not listed above may also occur in some people.

After taking ARTHREXIN

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

ARTHREXIN capsules are white and are marked with "IN-25".

Each bottle contains 50 capsules.

Ingredients

ARTHREXIN contains 25 mg of indometacin as the active ingredient.

The capsules also contain:

- lactose monohydrate
- sodium starch glycollate
- sodium lauryl sulfate

- magnesium stearate
- colloidal anhydrous silica
- gelatin
- titanium dioxide CI 77891

The capsules are gluten free.

Manufacturer

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

ARTHREXIN 25 mg capsules: AUST R 17586 (bottle)

ARTHREXIN 25 mg capsules: AUST R 17606 (blister pack -
not marketed)

This leaflet was prepared in
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