

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ARTHREXIN 100 mg suppositories

Indomethacin

Read all of this leaflet carefully before you start using ARTHREXIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ARTHREXIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ARTHREXIN is and what it is used for
2. What you need to know before you use ARTHREXIN
3. How to use ARTHREXIN
4. Possible side effects
5. How to store ARTHREXIN
6. Contents of the pack and other information

1. What ARTHREXIN is and what it is used for

ARTHREXIN belongs to a group of medicines called non-steroidal anti-inflammatory medicines (NSAIDs). These work by reducing the body's ability to produce inflammation,

which may cause pain and discomfort.

ARTHREXIN reduces fever, pain and inflammation.

Your doctor has prescribed ARTHREXIN for you because you are suffering from one of the following:

- Rheumatoid arthritis (disease mainly of the joints).
- Osteoarthritis (disease of the joints).
- Ankylosing spondylitis (a form of arthritis which mainly affects the back).
- Musculoskeletal disorders (muscle and bone disorders, such as tendonitis, inflammation in the joints, sprains and strains).
- Pain and swelling in gout (a form of arthritis in which crystals build up in the joints).
- Fever in Hodgkin's disease (a type of cancer).
- Pain, inflammation and swelling following orthopaedic surgery or nonsurgical procedures (associated with repositioning bones after dislocation or fracture).
- Pain, inflammation and swelling following dental surgical procedures.
- Period pain.
- Low back pain.
- A disease where the cartilage that serves as a cushion in the joints of the hips deteriorates (degenerative joint disease of the hip).
- Fever, the reduction of symptoms in some conditions which may produce fever (febrile conditions).

2. What you need to know before you use ARTHREXIN

Do not use ARTHREXIN:

- if you are hypersensitive (allergic) to indomethacin or any of the other ingredients of ARTHREXIN (listed in section 6).
- if you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had episodes of peptic ulcers, stomach bleeding or perforation.

- if you suffer from inflammation of the rectum causing soreness and bleeding from your anus (back passage).
- if you are taking medicine called triamterene for swelling and high blood pressure.
- if you are taking a medicine called diflunisal for pain, swelling, stiffness or joint pain.
- if you have nasal polyps (teardrop-shaped, non-cancerous growths) due to swelling of the area under the skin.
- if you have had a history of asthma attacks, hives or inflammation of the inside of the nose after taking aspirin or other NSAIDs, including ARTHREXIN.
- if you have a history of sensitivity (allergy) that causes swelling of the face and mouth (angioedema) after taking NSAIDs, including ARTHREXIN and/or aspirin.
- if you have heart failure or heart disease and/or cerebrovascular disease, e.g. if you have had a heart attack, stroke, or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages.
- if you have or have had problems with your blood circulation (peripheral arterial disease).
- if you have kidney or liver failure.
- if you are pregnant, do not use NSAIDs such as ARTHREXIN, at 30 weeks or later in your pregnancy because these medicines may cause problems in your unborn baby.
- if you are breastfeeding your baby.

Safety of ARTHREXIN in children has not been established.

Warnings and precautions

Take special care with ARTHREXIN:

ARTHREXIN may lead to serious heart problems (cardiovascular events), stomach or intestinal problems (gastrointestinal events), or skin reactions (cutaneous reactions) which may lead to death.

- if you develop a fever, severe skin rash or skin reaction or any unusual reaction such

as facial swelling when starting treatment with ARTHREXIN, stop using ARTHREXIN and tell your doctor immediately. These serious events may occur without warning and may be fatal, they include DRESS (drug rash with eosinophilia and systemic symptoms), Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN).

- if you have high blood pressure or have a tendency for fluid retention you should only be treated with ARTHREXIN after very careful consideration.
- if you have kidney or liver problems you should be closely monitored by your doctor to ensure that your kidney and liver function does not get worse.
- if you have high levels of sugar in the blood (diabetes).
- if you smoke or have high levels of bad cholesterol in the blood.
- if you are taking a diuretic (water tablet) to increase the amount of urine that is excreted,
- if you are feeling thirsty, tired, have a dry mouth, feeling dizzy or light-headed, you may be dehydrated.
- if you experience heart palpitations, shortness of breath, chest pain, nausea, or vomiting, you may have high levels of potassium in your blood (hyperkalaemia).
- if you have asthma.
- if you are epileptic (have seizures), as you may need to stop treatment with ARTHREXIN.
- if you have Parkinson's disease, as you may need to stop treatment with ARTHREXIN.
- if you have any psychiatric disease.
- if you suffer from systemic lupus erythematosus (SLE), an auto immune disorder, you may have an increased risk of inflammation of the membrane covering the brain (aseptic meningitis).
- if you suffer from rectal bleeding (bleeding from the back passage).
- if you experience dizziness and headaches with the use of ARTHREXIN you may

need to stop using ARTHREXIN as ARTHREXIN can aggravate the headaches.

- if you experience a recurrent inclination to empty the bowel, or irritation in the anus (back passage) area with the use of ARTHREXIN.
- if you have an infection, since symptoms such as fever and inflammation may be masked. If you use this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- if you notice any change in your vision, you should see your doctor. If you have rheumatoid arthritis your doctor may want to examine your eyes at intervals during your treatment with ARTHREXIN.
- if you are having blood tests done, make sure that the doctor doing them knows that you are using ARTHREXIN. Misleading results have been seen with patients having a dexamethasone suppression test (DST) while using ARTHREXIN.
- if you are elderly or you have previously had stomach ulcers, you have a higher risk of getting side effects, especially from the stomach. Your doctor should therefore prescribe the lowest dose that gives you sufficient relief. If you experience any unusual symptoms from the stomach, you must tell your doctor about it.
- if you have a digestive tract disorder.
- if you have a problem with your blood clotting.
- if you are anaemic (low red blood count that leaves you feeling very tired).
- Taking NSAIDs, such as ARTHREXIN, at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to be treated with NSAIDs, such as ARTHREXIN, for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not use NSAIDs, such as ARTHREXIN, around 30 weeks of pregnancy or later.
- if you have difficulty becoming pregnant.
- if you suffer from porphyria.

Children

ARTHREXIN must not be used in children.

Other medicines and ARTHREXIN

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Anti-coagulants such as warfarin (used to prevent blood clots).
- Other non-steroidal anti-inflammatory medicines (NSAIDs) including diflunisal or aspirin (used to treat pain and inflammation). Avoid using two or more NSAID's as this may increase the risk of experiencing adverse effects.
- Antacids, that are used to neutralise stomach acidity and are used to relieve heartburn, indigestion or an upset stomach.
- Sulfonylureas and other medicines used to treat diabetes, as your doctor may need to adjust the dose.
- Probenecid (also used to treat gout).
- Methotrexate (used to treat certain types of cancer or autoimmune disorders).
- Ciclosporin (used to prevent rejection of a transplanted organ).
- Lithium (used to treat mood disorders).
- Diuretics such as furosemide and triamterene and other medicines used to treat high blood pressure.
- Phenylpropanolamine (used in cold and flu medicines).
- Mifepristone (used to abort pregnancy).
- Medicines used to treat heart disorders (such as digoxin).
- Corticosteroids (used to treat painful or inflammatory conditions or allergies).
- Quinolone antibiotics (used to treat certain bacterial infections).
- Phenytoin (used to treat epilepsy/seizures).

- Antiretrovirals (used to treat viral infections such as HIV).
- Muscle relaxants.
- Tacrolimus, medicine that lowers the risk of organ rejection after an organ transplant.
- Tiludronic acid, medicine used to treat Paget's disease (broken and deformed bones and pain in the affected area).
- Selective serotonin reuptake inhibitors (SSRIs), medicine used to treat depression.
- Vancomycin used to treat bacterial infections such as colitis.

Pregnancy, breastfeeding and fertility

You should not use ARTHREXIN if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using ARTHREXIN.

Pregnancy

You should not use ARTHREXIN if you are already at 30 weeks or later in your pregnancy. ARTHREXIN must not be used at 30 weeks or later in your pregnancy since it may cause major heart, lung and kidney disorders in the unborn child. If used at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions delaying the onset of delivery.

Breastfeeding

You should not use ARTHREXIN if you are breastfeeding your baby.

Fertility

Using ARTHREXIN suppositories may make it more difficult to become pregnant.

Driving and using machines

Since adverse reactions such as dizziness, drowsiness and visual disturbances have been reported in patients receiving ARTHREXIN, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that ARTHREXIN does not adversely affect your ability to do so safely.

It is not always possible to predict to what extent ARTHREXIN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ARTHREXIN affects you.

3. How to use ARTHREXIN

Do not share medicines prescribed for you with any other person.

Always use ARTHREXIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

Adults

The usual adult dosage is one suppository to be inserted into the back passage once or twice a day. One should be used at bedtime and if another is necessary it should be used in the morning.

Do not use more than two suppositories in divided doses (200 mg) a day.

ARTHREXIN must not be taken by mouth.

ARTHREXIN must be placed inside your back passage (rectum).

Remove the suppository from the foil and lying on your back or your side with your knees bent up, push the suppository, with the pointed end first, up into your back passage.

Lie still for a minute or so, and then wash your hands.

The suppository should remain in place and dissolve completely.

The amount you use will depend upon your condition.

Your doctor will tell you how long your treatment with ARTHREXIN will last. Do not stop

treatment early. If you have the impression that the effect of ARTHREXIN is too strong or too weak, tell your doctor or pharmacist.

ARTHREXIN is not recommended for use in children.

If you use more ARTHREXIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use ARTHREXIN

Do not use a double dose to make up for forgotten individual doses.

If you forget to use the suppository, use it as soon as you remember. If it is nearly time for your next dose, just carry on with the next dose as normal.

4. Possible side effects

ARTHREXIN can have side effects.

Not all side effects reported for ARTHREXIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ARTHREXIN, please consult your healthcare provider for advice.

If any of the following happens, stop using ARTHREXIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN), Drug Rash with Eosinophilia and System Symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to ARTHREXIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Difficulty in breathing (especially if you suffer from, or have a history of asthma or allergic disease, cough, feeling tired, wheezing),
- swelling of legs, ankles and feet, fatigue and weakness, shortness of breath, lack of appetite, swelling of abdomen, rapid or irregular/abnormal heartbeat, chest pain (heart failure),
- infection in the soft tissue that spreads rapidly and eats away at the flesh,
- signs of muscle weakness, nausea, heart palpitations, irregular heartbeat and abnormal blood pressure,
- sudden or unusual fatigue, weight loss, frequent infections and easy bleeding or bruising (these may be symptoms of leukaemia),
- pale skin, tiredness, fever, sore throat and mouth, small red spots on the skin, bruising or prolonged bleeding after injury, severe chills, mouth ulcers, headache, shortness of breath and dizziness; these may be symptoms of blood disorders,
- abnormal heart rhythm, tiredness or weakness, which may be symptoms of too much potassium in the blood,
- feeling severely depressed or confused including thinking about suicide, seeing or hearing things that are not there (hallucinations),
- nausea, vomiting blood, tenderness when touching the stomach (pancreatitis),
- lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease),
- inflammation of the mouth and stomach (ulcerative stomatitis),
- passing blood in your faeces (stools/motions),
- vomit any blood or dark particles that look like coffee grounds (haematemesis),

- deafness,
- yellowing of the skin and eyes, also called jaundice,
- intense itching, dark urine, light coloured stools, pain in the upper right portion of your abdomen (gall stones),
- fits or seizures (convulsions),
- coma,
- shortness of breath, decreased urine output, drowsiness, fluid retention causing swelling in your legs, ankles or feet, confusion, nausea, chest pain or pressure (kidney failure),
- pink-red blotches and/or bumps on the skin,
- inflammation of the walls of small blood vessels (angiitis), redness, sudden swelling in the leg or arm with tenderness and feeling of increased warmth (thrombophlebitis),
- loss of sensation, numbness, tingling, and pricking sensations, sensitivity to touch (peripheral neuropathy),
- reduction in the amount of urine passed (acute renal failure),
- bleeding, burning, pain, discomfort and itching of the back passage.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Bruising (bleeding into the skin),
- nausea, vomiting, constipation, diarrhoea, loss of appetite (anorexia), stomach ulcers, abdominal pain,
- tiredness (including feeling unwell and listlessness),
- headache,
- dizziness and light-headedness,
- sensation that things around you are moving (vertigo).

Less frequent side effects:

- High blood sugar presenting with symptoms like frequent urination, increased thirst, blurred vision, fatigue (hyperglycaemia),
- sugar in the urine, confirmed by laboratory test or dipstick test (glycosuria),
- mental disorders including a loss of personal identity,
- bleeding from the nose,
- sleeplessness,
- anxiety,
- drowsiness,
- involuntary muscle movements,
- pins and needles (paraesthesia),
- speech problems (dysarthria),
- worsening of epilepsy and parkinsonism symptoms (symptoms that mimic those of Parkinson's disease such as tremor or abnormal movements),
- blurred vision, double vision, pain in the eye, other visual disturbances,
- ringing in the ears (tinnitus),
- the feeling that you need to pass stools, even though your bowel is already empty (tenesmus),
- trapped wind,
- indigestion or heartburn (dyspepsia),
- hair loss (alopecia),
- increased sensitivity of the skin to sun and ultraviolet light (photosensitivity),
- a rash of purple and/or tiny brown-purple spots or discolouration of the skin,
- scaly and peeling skin (exfoliative dermatitis),
- sweating,
- flushing,
- bleeding from the vagina in woman,

- swelling (oedema),
- weight gain,
- breast changes including enlargement and tenderness in men and women (gynaecomastia),
- high or low blood pressure (hypertension or hypotension),
- protein and blood in the urine as well as increased levels of urea in the blood. These changes in urine and blood composition would normally be picked up in urine or blood tests.

Side effects with an unknown frequency:

- Diarrhoea (if severe), weight loss, fever and/or abdominal pain (regional ileitis),
- abnormal liver function,
- aggravation of psoriasis (inflamed patches get bigger and spread faster),
- accelerated breakdown of cartilage in the joints,
- muscle weakness,
- abnormal laboratory test results.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: <https://www.sahpra.org.za/health-productsvigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of ARTHREXIN.

5. How to store ARTHREXIN

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What ARTHREXIN contains

The active substance is 100 mg of indomethacin.

The other ingredient is Suppocire AS2.

Sugar free

What ARTHREXIN looks like and contents of the pack

ARTHREXIN is a cream coloured, torpedo-shaped mass.

10 suppositories packed in white opaque polyvinylchloride laminated to polyethylene. One or more strips are packed into an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and

Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: BOT0600848 S2

Namibia: NS2 90/3.1/00796

Zimbabwe: P.P.92/3.1/2610