

ARTHREXIN

Indomethacin 100mg Suppositories

What is in this leaflet

This leaflet answers some common questions about ARTHREXIN. It does not contain all the information available on this medicine. 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 expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet. You may want to read it again.

What ARTHREXIN is used for and how it works

Your ARTHREXIN suppositories contain the active ingredient Indomethacin. It belongs to a group of medicines known as the NSAIDs (non steroidal anti-inflammatory drugs).

ARTHREXIN is used to relieve the pain and inflammation (swelling, redness, soreness) that may occur in the following:

- Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis
- Degenerative joint disease of the hip
- Gout
- Muscle and bone injuries such as bursitis, tendonitis (tennis elbow), sprains and strains, low back pain (lumbago)
- Pain and swelling after setting broken or dislocated bones
- Period pain

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

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

ARTHREXIN is available on prescription from your doctor.

Before you take ARTHREXIN

When you must not take it

Do not take ARTHREXIN if:

- **You are allergic to Indomethacin or any of the other ingredients listed at the end of this leaflet**
- **You have developed an asthmatic attack, runny nose or itchy skin as a result of using aspirin or other NSAIDs in the past**
- **You have a peptic ulcer (ie. a stomach or duodenal ulcer) or a history of ulcers**
- **You have a history of rectal inflammation or bleeding**
- **You are pregnant or planning on becoming pregnant**
- **You are breastfeeding or planning on breastfeeding**

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.

Before you take it

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

- Heartburn or indigestion
- Stomach ulcers or other stomach problems
- Bowel or intestinal problems such as ulcerative colitis
- Vomiting blood or bleeding from the back passage
- Diabetes
- High blood pressure
- Heart problems
- Swelling of the feet or ankles
- Mental disturbances
- Epilepsy (seizures or fits)
- Parkinson's disease
- Any current infection
- A tendency to bleed or other blood problems
- Renal problems
- Liver problems
- Asthma
- Fluid retention
- A dependency on alcohol
- Are or have been a heavy cigarette smoker

Your doctor may want to take special care if you have any of these conditions.

Caution is advised in the elderly.

Taking other medicines

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

Medicines that may interfere with ARTHREXIN include:

- Aspirin or other NSAIDs
- Warfarin, used to prevent blood clots
- Probenecid, used for gout
- Methotrexate, used to treat arthritis and certain types of cancers
- Cyclosporin, used to prevent organ transplant rejection or treat immune system problems
- Lithium, used to treat mood swings
- Digoxin, used to treat heart failure or irregular heart beats
- Medicines used to treat high blood pressure
- Diuretics, also known as fluid tablets

These medicines may be affected by ARTHREXIN or may affect how well ARTHREXIN works. This may mean that you need different amounts of your medicines or that you need to take a different medicine. Therefore, it is important that you discuss this with your doctor or pharmacist.

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

How to take ARTHREXIN properly

How much to take

Your doctor will tell you how much ARTHREXIN you need to take each day. It is important that you take ARTHREXIN as directed by your doctor. Do not take more than the recommended dose.

The usual daily dose of ARTHREXIN is between 50 and 200mg daily in divided doses. Your doctor will tell you how many suppositories you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.

Your doctor may start you on a low dose of ARTHREXIN 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 ARTHREXIN. It is important that you only change the dose if your doctor advises you to do so.

Elderly patients can be more susceptible to the risk of adverse reactions and therefore, in general, lower dosages are recommended.

The use of ARTHREXIN is not recommended for children.

How long to take it

ARTHREXIN helps to control your condition but does not cure it. Depending on your condition, you may need ARTHREXIN for a few days, a few weeks or for longer periods. Continue taking ARTHREXIN for as long as your doctor recommends.

If you forget a dose

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking ARTHREXIN

Tell all doctors, dentists and pharmacists who are treating you that you are taking ARTHREXIN.

Before you start any new medicine, tell your doctor or pharmacist that you are taking ARTHREXIN.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking ARTHREXIN.

If you get an infection while taking ARTHREXIN, tell your doctor. ARTHREXIN may hide some of the signs of an infection (such as pain, fever, redness or swelling). You may mistakenly think that you are better or that your infection is not serious.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking ARTHREXIN. It may cause prolonged bleeding and may need to be stopped before surgery.

Your doctor may ask you to have tests to check your blood, kidneys, liver or eyes. This helps to prevent unwanted side effects.

If you have to have any other blood tests, tell your doctor that you are taking ARTHREXIN.

Do not take ARTHREXIN to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

ARTHREXIN may cause dizziness or tiredness in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that ARTHREXIN does not affect your performance.

Side effects

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

All medicines can have some unwanted 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.

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

- Headache, dizziness, lightheadedness
- Tiredness, drowsiness, confusion
- Stomach upset such as nausea, vomiting, heartburn or indigestion
- Loss of appetite
- Constipation, diarrhoea, pain in the stomach
- Change in mood such as depression

These are the more common side effects of ARTHREXIN.

Tell your doctor as soon as possible if you experience:

- Severe pain or tenderness in the stomach
- Tingling or numbness of the hands or feet
- Muscle weakness, or uncontrollable movements
- Fast or irregular heartbeats
- Signs of frequent infections, such as fever, severe chills, sore throat or mouth ulcers
- Bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- Signs of anaemia, such as tiredness, being short of breath and looking pale
- A change in the amount or frequency of urine passed, burning feeling when passing urine
- Swelling of the ankles or legs
- Yellowing of the skin or eyes (jaundice)
- Eye problems such as blurred vision or pain
- Skin rash or hypersensitivity

Stop taking ARTHREXIN and tell your doctor immediately, or go to the Emergency department at the nearest hospital if you notice any of the following

- Vomiting blood or material that looks like coffee grounds
- Bleeding from the back passage, black sticky bowel motions or bloody diarrhoea

- 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
- Increased seizures or fits
- Pain or tightness in the chest

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

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

You should only take the number of suppositories that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any ARTHREXIN by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of ARTHREXIN with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the label or if the packaging shows signs of tampering.

Keep your ARTHREXIN suppositories in their packaging until it is time to use them.

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store ARTHREXIN, or any other medicine, in the bathroom or near a sink.

Disposal

If your doctor tells you to stop taking ARTHREXIN or if the suppositories have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What ARTHREXIN Suppositories look like

ARTHREXIN 100mg suppositories are cream coloured, torpedo shaped suppositories. Each suppository is approximately 25mm long and 9mm across its widest point.

Each ARTHREXIN suppository contains 100mg of the active ingredient Indomethacin.

Each ARTHREXIN suppository also contains suppicire (semi-synthetic glycerides).

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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2 February 2009
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