

Arthrix Capsules 100 mg and 200 mg (Celecoxib Capsules 100 mg and 200 mg)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called **Arthrix Capsules** and has two strengths **100 mg and 200 mg**. Please refer to your doctor prescription. The below instructions will be referred to as **Arthrix Capsules** for all strengths throughout the remainder of this leaflet.

What is this leaflet:

1. What Arthrix Capsules are and what they are used for
2. What you need to know before you take Arthrix Capsules
3. How to take Arthrix Capsules
4. Possible side effects
5. Further information

1. What Arthrix Capsules are and what they are used for

Arthrix Capsules are used in adults for the relief of symptoms of **rheumatoid arthritis, osteoarthritis and ankylosing spondylitis**. Arthrix Capsules belong to a group of medicinal products called non-steroidal anti-inflammatory drugs (NSAID), and specifically a sub-group known as COX-2 inhibitors. Your body makes prostaglandins which may cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. Arthrix Capsules act by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

2. What you need to know before you take Arthrix Capsules

You have been prescribed Arthrix Capsules by your doctor. The following information will help you to get the best results with Arthrix Capsules. If you have any further questions please ask your doctor or pharmacist.

Do not take Arthrix Capsules

Tell your doctor if any of the following are true for you as patients with these conditions should not take Arthrix Capsules.

- if you are allergic to celecoxib or any of the other ingredients of Arthrix Capsules (listed in Section 6)
- if you have had an allergic reaction to a group of medicines called 'sulphonamides' (e.g. some antibiotics used to treat infections)
- if you currently have an ulcer in your stomach or intestines, or bleeding in your stomach or intestines
- if as a result of taking acetylsalicylic acid or any other anti-inflammatory and pain relieving medicines (NSAID) you have had asthma, nose polyps, severe nose congestion, or an allergic reaction such as an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or wheezing
- if you are pregnant. If you can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor
- if you are breast-feeding
- if you have severe liver disease
- if you have severe kidney disease
- if you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease
- if you have heart failure, established ischaemic attack (temporary reduction of blood flow to the brain, also known as 'mini-stroke'), angina, or blockages of blood vessels to the heart or brain
- if you have or have had problems with your blood circulation (peripheral arterial disease) or if you have had surgery on the arteries of your legs

Warnings and precautions

Talk to your doctor before taking Arthrix Capsules:

- if you have previously had an ulcer or bleeding in your stomach or intestines. (Do not take Arthrix Capsules if you currently have an ulcer or bleeding in your stomach or intestines)
- if you are taking acetylsalicylic acid (even at low dose for heart protective purposes)
- if you use medicines to reduce blood clotting (e.g. warfarin/variante like anticoagulants or oral anti-clotting medicines, e.g. apixaban)
- if you use medicines called corticosteroids (e.g. prednisone)
- if you are using Arthrix Capsules at the same time as other non-steroidal NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided
- if you smoke, have diabetes, raised blood pressure or raised cholesterol
- if your heart, liver or kidneys are not working well your doctor may want to keep a regular check on you
- if you have fluid retention (such as swollen ankles and feet)
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (used to treat excess fluid in the body)
- if you have had a serious allergic reaction or a serious skin reaction to any medicines
- if you feel ill due to an infection or think you have an infection, as Arthrix Capsules may mask a fever or other signs of infection and inflammation
- if you are over 65 years of age your doctor will want to monitor you regularly
- the consumption of alcohol and NSAIDs may increase the risk of gastrointestinal problems

As with other NSAIDs (e.g. ibuprofen or diclofenac) this medicine may lead to an increase in blood pressure, and so your doctor may ask to monitor your blood pressure on a regular basis.

Some cases of severe liver reactions, including severe liver inflammation, liver damage, liver failure (some with fatal outcome) or require liver transplant, have been reported with celecoxib.

Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment.

Arthrix Capsules may make it more difficult to become pregnant. If you should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant (see section on Pregnancy and Breast-feeding).

Other medicines and Arthrix Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- Dexamethopran (used to treat coughs)
- ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics (used for high blood pressure and heart failure)
- Flucanazole and rifampicin (used to treat fungal and bacterial infections)
- Warfarin or other warfarin like medicines ('blood-thinning' agents that reduce blood clotting) including newer medicines like apixaban
- Lithium (used to treat some types of depression)
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat
- Neuroleptics (used to treat some mental disorders)
- Methoprene (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Calcium channel blockers (used to treat epilepsy/seizures and some types of pain or depression)
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders)
- Clozapine and tacrolimus (used for immune system suppression e.g. after transplant)

Arthrix Capsules can be taken with low dose acetylsalicylic acid (75 mg or less daily). Ask your doctor for advice before taking both medicines together.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Arthrix Capsules must not be used by women who are pregnant or can become pregnant (i.e. women of child bearing potential who are not using adequate contraception) during ongoing treatment. If you become pregnant during treatment with Arthrix Capsules you should discontinue the treatment and contact your doctor for alternative treatment.

Breast-feeding

Arthrix Capsules must not be used during breast-feeding.

Fertility

NSAIDs, including Arthrix Capsules, may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

You should be aware of how you react to Arthrix Capsules before you drive or operate machinery. If you feel dizzy or drowsy after taking Arthrix Capsules, do not drive or operate machinery until these effects wear off.

Important information about some of the ingredients of Arthrix Capsules

Arthrix Capsules contain lactose in the form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Arthrix Capsules

Always take Arthrix Capsules exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you think or feel that the effect of Arthrix Capsules is too strong or too weak, talk to your doctor or pharmacist. Your doctor will tell you what dose you should take. As the risk of side effects associated with heart problems may increase with dose and duration of use, it is important that you use the lowest dose that controls your pain and you should not take Arthrix Capsules for longer than necessary to control symptoms.

Method of administration

Arthrix Capsules are for oral use. The capsules can be taken at any time of the day, with or without food. However, to take each dose of Arthrix Capsules at the same time each day. Contact your doctor within two weeks of starting treatment if you do not experience any benefit.

The recommended dose is:

- For osteoarthritis the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

- one 200 mg capsule once a day, or
- one 100 mg capsule twice a day

For rheumatoid arthritis the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

- one 100 mg capsule twice a day.

For ankylosing spondylitis the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

- one 200 mg capsule once a day, or
- one 100 mg capsule twice a day.

Kidney or liver problems: make sure your doctor knows if you have liver or kidney problems so you may need a lower dose.

The elderly, especially those with a weight less than 50 kg: if you are over 65 years of age and especially if you weigh less than 50 kg, your doctor may want to monitor you more closely.

Use in children

Arthrix Capsules are for adults only, it is not for use in children.

If you take more Arthrix Capsules than you should:

You should not take more capsules than your doctor tells you. If you take too many capsules contact your doctor, pharmacist or hospital and take your medicine with you.

If you forget to take Arthrix Capsules:

If you forget to take a capsule, take it as soon as you remember. Do not take a double dose to make up for forgotten doses.

If you stop taking Arthrix Capsules:

Suddenly stopping your treatment with Arthrix Capsules unless your doctor tells you to, your doctor may tell you to reduce the dose over a few days before stopping completely. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Arthrix Capsules can have side-effects, although not everybody gets them.

The side effects listed below were observed in arthritis patients who took Celecoxib. Side effects marked with an asterisk (*) are listed below at the higher frequencies that occurred in patients who took Celecoxib to prevent colorectal patients in these studies took Celecoxib at high doses and for a long duration.

If any of the following happen, stop taking Arthrix Capsules and tell your doctor immediately:

- If you have:
- an allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing
 - heart problems such as pain in the chest
 - severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or blood-stained stools, or vomiting blood
 - a skin reaction such as rash, blistering or peeling of the skin
 - liver failure symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow).

Very common: may affect more than 1 in 10 people

- High blood pressure, including worsening of existing high blood pressure*

- Common: may affect up to 1 in 10 people**
- Heart attack
 - Fluid build up with swollen ankles, legs and/or hands
 - Urinary infections
 - Shortness of breath*, sinusitis (sinus inflammation, sinus infection, blocked or painful sinuses), blocked or runny nose, sore throat, coughs, colds, flu-like symptoms
 - Dizziness, difficulty sleeping
 - 'Vomiting', stomach ache, diarrhoea, indigestion, wind
 - Rash, itching
 - Muscle stiffness
 - Difficulty swallowing*
 - Headache
 - Nausea (feeling sick)
 - Painful joints
 - Worsening of existing allergies
 - Accidental injury

- Uncommon: may affect up to 1 in 100 people**
- Sticks*
 - Heart failure, palpitations (awareness of heart beat), fast heart rate
 - Abnormalities in liver-related blood tests
 - Abnormalities in kidney-related blood tests
 - Anaemia (changes in red blood cells that can cause fatigue and breathlessness)
 - Anxiety, depression, tiredness, drowsiness, tingling sensations (pins and needles)
 - High levels of potassium in blood test results (can cause nausea (feeling sick), fatigue, muscle weakness or palpitations)
 - Impaired or blurred vision, ringing in the ears, mouth pain and sores, difficulty hearing*
 - Constipation, burping, stomach inflammation (indigestion), stomach ache or vomiting, worsening of inflammation of the stomach or intestine
 - Leg cramps
 - Passed itchy rash (hives)
 - Eye inflammation
 - Difficulty breathing
 - Skin discoloration (bruising)
 - Chest pain (not related pain not related to the heart)
 - Face swelling

- Rare: may affect up to 1 in 1,000 people**
- Ulcers (bleeding) in the stomach, gut or intestines; or rupture of the intestine (can cause stomach ache, fever, nausea, vomiting, intestinal blockage), dark or black stools, inflammation of the pancreas (can lead to stomach pain), inflammation of the gut (oesophagus)
 - Low levels of sodium in the blood (a condition known as hyponatraemia)
 - Reduced number of white blood cells (which help to protect the body from infection) or blood platelets (increased chance of bleeding or bruising)
 - Difficulty coordinating muscular movements
 - Feeling confused, changes in the way things taste
 - Increased sensitivity to light
 - Swell of hair
 - Hallucinations
 - Bleeding in the eye
 - Acute reaction that may lead to lung inflammation
 - Irregular heartbeat
 - Flushing
 - Blood clot in the blood vessels in the lungs. Symptoms may include sudden breathlessness, sharp pains when you breathe or collapse
 - Bleeding of the stomach or intestines (can lead to bloody stools or vomiting, inflammation of the intestine or colon)
 - Severe liver inflammation (hepatitis). Symptoms may include nausea (feeling sick), diarrhoea, jaundice (yellow discoloration of the skin or eyes), dark urine, pale stools, bleeding easily, itching or chills
 - Acute kidney failure
 - Drug-induced lupus
 - Swelling of the face, lips, mouth, tongue or throat, or difficulty swallowing

- Very rare: may affect up to 1 in 10,000 people**
- Serious allergic reactions (including potentially fatal anaphylactic shock)
 - Serious skin conditions such as Stevens-Johnson syndrome, and/or toxic dermatitis and toxic epidermal necrolysis (can cause rash, blistering or peeling of the skin) and acute generalised exanthematous pustules
 - Symptoms include the skin becoming red with swollen areas covered in numerous small pustules)
 - A delayed allergic reaction with possible symptoms such as rash, swelling of the face, fever, swollen glands, and abnormal test results (e.g. liver, blood cell count), a type of rapid white blood cell count)
 - Bleeding within the brain, causing death
 - Meningitis (inflammation of the membrane around the brain and spinal cord)
 - Liver failure, liver damage and severe liver inflammation (fulminant hepatitis) (sometimes fatal or requiring liver transplant). Symptoms may include nausea (feeling sick), diarrhoea, jaundice (yellowing of the skin or eyes), dark urine, pale stools, bleeding easily, itching or chills
 - Liver problems (such as cholestasis and cholelithiasis), which may lead to complications by symptoms such as discoloured stool, nausea and yellowing of the skin or eyes)
 - Inflammation of the kidneys and other kidney problems (such as nephritic syndrome and minimal change disease, which may be accompanied by symptoms such as water retention (oedema), tarry urine, itchy and a loss of appetite)
 - Worsening of epilepsy (possible more frequent and/or anterior severe seizures)
 - Bleeding of an artery or vein in the leg leading to partial or complete loss of vessel
 - Inflamed blood vessels (can cause fever, aches, purple blotches on the skin)
 - A reduction in the number of red and white blood cells and platelets risk may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections)
 - Stomach pain and weakness
 - Impaired sense of smell
 - Loss of taste

Not known: frequency cannot be estimated from the available data

- Decreased fertility as females, which is usually reversible on discontinuation of the medicine.

In clinical studies not associated with Arthrix or other arthrix conditions, where Celecoxib was taken at doses of 400 mg per day for up to 3 years, the following additional side effects have been observed:

Common: may affect up to 1 in 10 people

- Heart problems: angina (chest pain)
- Stomach problems: intestinal bowel syndrome (can include stomach ache, diarrhoea, indigestion, wind)
- Kidney stones (which may lead to stomach or back pain, blood in urine), difficulty passing urine
- Weight gain

Uncommon: may affect up to 1 in 100 people

- Deep vein thrombosis (blood clot usually in the leg, which may cause pain, swelling or redness of the calf or breathing problems)
- Stomach problems: stomach infection (which can cause irritation and ulcers of the stomach and intestines)
- Lower limb fracture
- Shingles, skin infection, eczema (dry itchy rash), pneumonia (chest infection (possibly cough, fever, difficulty breathing))
- Flashes in the eye caused blurred or impaired vision, vertigo due to inner ear trouble, sore, inflamed or bleeding gums, mouth sores
- Excessive urination at night, bleeding from piles/ haemorrhoids, frequent bowel movements
- Fatty lumps in skin or elsewhere, ganglion cyst (harmless swelling on or around joints and tendons in the hand or foot), difficulty speaking, abnormal or very heavy bleeding from the vagina, breast pain
- High levels of sodium in blood test results

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Arthrix Capsules

- Keep out of the reach and sight of children.
- Do not use Arthrix Capsules after the expiry date stated on the blister and carton. The expiry date refers to the last day of that month.
- Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What Arthrix Capsules contain

Arthrix Capsules 100 mg

Each capsule contains: Celecoxib 100 mg Ph.Eur.

The other ingredients are: Lactose Monohydrate, Croscarmellose sodium, Povidone, Sodium Lauryl Sulfate, Magnesium Stearate.

Arthrix Capsules 200 mg

Each capsule contains: Celecoxib 200 mg Ph.Eur.

The other ingredients are: Lactose Monohydrate, Croscarmellose sodium, Povidone, Sodium Lauryl Sulfate, Magnesium Stearate.

What Arthrix Capsules look like?

Arthrix Capsules 100 mg

Off white cap / Off white body size 2^o hard gelatin capsule, printed with 'C100' in green ink on cap, filled with white to off white granular powder.

Arthrix Capsules 200 mg

Off white cap / Off white body size 2^o hard gelatin capsule printed with 'C200' in golden yellow ink on cap, filled with white to off white granular powder.

How supplied:

- Arthrix Capsules 100 mg are supplied in Blister pack.
- Box of 20 blistered capsules (2x10's)
- Box of 30 blistered capsules (3x10's)

Arthrix Capsules 200 mg

- Arthrix Capsules 200 mg are supplied in Blister pack.
- Box of 10 blistered capsules (1x10's)
- Box of 30 blistered capsules (3x10's)

INSTRUCTIONS TO THE PATIENT
This is a Medication

- Medication is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and pharmacist are experts in medicine, as benefits and risks.
- Do not try yourself! Respect the period of treatment prescribed for you.
- Do not expect the same prescription without consulting your doctor.

KEEP MEDICATION OUT OF THE REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists

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