

Arthrix Capsules 100 mg and 200 mg

(Celecoxib Capsules 100 mg and 200 mg)

Read all of the **Important Information** 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 can affect your liver. It may cause liver damage or 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 that do not go away.

Your medicine is called **Arthrix Capsules** and have 2 strengths 100 mg and 200 mg. Please refer to your doctor's prescription. The below instructions apply to both strengths of Arthrix Capsules for all strengths throughout the remainder of this leaflet.

What is in this leaflet?

1. What are Arthrix Capsules 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. How to store Arthrix Capsules
6. Other information

What are Arthrix Capsules and what they are used for

Arthrix Capsules are used in adults for the relief of signs and symptoms of osteoarthritis (degenerative joint disease) and ankylosing spondylitis. Ankylosing spondylitis is a group of medical problems involving the axial and peripheral anti-inflammatory drugs (NSAID), and specifically a subgroup known as (COX-2) inhibitors which mostly prevent the pain and inflammation of the body makes more of these. Arthrix Capsules aid by reducing the production of prostaglandins which are substances that cause pain and inflammation.

In conditions such as osteoarthritis and ankylosing spondylitis, the body makes more of these. Arthrix Capsules aid by reducing the production of prostaglandins which are substances that cause pain and inflammation.

You should expect your medicine to start working within hours of taking the first dose, but you may not experience a full effect for several days.

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 get the best results with Arthrix Capsules. If you have any further questions, 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 those conditions should not take this medicine:

- If you are allergic to celecoxib or any of the other ingredients of Arthrix Capsules listed in Section 6.
- If you are currently taking a group of medicines called "sophoramides" (e.g. some antibiotics used to treat infections).
- If you currently have an ulcer in your stomach or intestines, or bleeding in your stomach.
- If as a result of taking acetylsalicylic acid or with other anti-inflammatory and pain relieving medicines (NSAID) you had bad side effects, nosebleeds, severe diarrhoea, or any other reaction as an ulcer in your stomach, swelling of the face, loss, tongue or breath, breathing difficulties or wheezing if you are pregnant. If you can become pregnant during treatment you should tell your doctor about the contraceptive with your doctor.
- If you are breast-feeding.
- If you have severe heart disease.
- If you have ever had kidney disease.
- If you have an inflammatory disease of the intestines such as ulcerative colitis.
- If you have heart failure, established ischaemic heart disease, or cerebrovascular disease, e.g., you have been diagnosed with a heart attack, stroke, or transient ischaemic attack (TIAs).
- If you have had a stroke, as well as reduced blood flow to the brain; also known as "ministroke"; anaemia, or blockages of blood vessels to the heart or brain.
- If you have had a heart attack or if you have had surgery on the arteries of your legs.

Warnings and precautions:

- Tell 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 in your stomach or intestines or bleeding in your stomach.)
 - If you are taking acetylsalicylic acid at levels low for heart protective purposes
 - If you use other medicines to reduce blood clotting (e.g. warfarin or warfarin-like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban)
 - If you use medical devices or contraceptives (e.g., condoms).
 - If you are taking Arthrix Capsules at the same time as other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or diclofenac. The use of these medicines together should be avoided.
 - If you have diabetes, raised blood pressure or raised cholesterol. If your heart, liver or kidneys are not working well your doctor may want to refer a regular check on you.
 - If you have varicose veins (such as swollen ankles and feet).
 - If you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (water-extract fluids) in a serious way.
 - If you have had a heart attack or a serious skin reaction to any medicines you are taking.
 - If you are at risk of 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 for side effects. 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 your 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 and liver failure (either fatal outcome or requiring liver transplant), have been reported with celecoxib.

If the cases that reported time to onset, most severe liver reactions occurred within 3 months of starting treatment with celecoxib.

Arthrix Capsules may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. If you are pregnant or planning to become pregnant and NSAIDs may increase the risk of pregnancy and breast-feeding.

Other medicines and Arthrix Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might be taking any of the following:

- Dextromethorphan (used to treat coughs)
- ACE inhibitors, angiotensin receptors, beta-blockers and diuretics (used for heart disease, hypertension and heart failure)
- Flucosazole and rilampicin (used to treat fungal and bacterial infections)
- Warfarin or other anti-clotting medicines or other medicines that reduce blood clotting including some medicines like apixaban
- Lithium (used to treat types of depression)
- Oral contraceptives, depression, sleep disorders, high blood pressure or an irregular heartbeat.
- Neuroleptics (used to treat schizophrenia)
- Metformin (used to treat type 2 diabetes, gout and leukaemia)
- Carbamazepine (used to treat epilepsies/ seizures and some forms of pain or depression)
- Ibuprofen (used to treat epilepsies/ seizures and some sleep disorders)
- Ciclosporin and tacrolimus (used for immune system suppression e.g., after transplants)

Arthrix Capsules should 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Programmatic use:

Arthrix Capsules must not be taken by women who are pregnant or become pregnant (i.e. women who are still not pregnant but who are not using adequate contraceptive 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.

Particular care:

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 or vehicles, especially after taking Arthrix Capsules, or drive or operate machinery until these effects wear off.

Important information about some of the ingredients of Arthrix Capsules

Arthrix Capsules contain the active ingredient Celecoxib. If you have any concerns about this medicine, ask your doctor or pharmacist. If you have any concerns about this medicine, ask your doctor or pharmacist.

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 not strong enough, do not take a double dose.

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 to take the correct dose. If you are taking Arthrix Capsules, 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, try to take each dose of Arthrix Capsules at the same time each day. Contact your doctor within two weeks of starting treatment if you are not getting the relief you expect.

The recommended dose:

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 100 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.

Kidney or liver problems: make sure your doctor knows if you have liver or kidney problems, especially those with 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 reduce the dose.

You should not take more than 400 mg per day.

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:

If you take more Arthrix Capsules than you should, take as soon as you remember. Do not take a double dose to make up for forgotten doses.

If you stop taking Arthrix Capsules:

Sudden stopping of treatment with Arthrix Capsules may lead to your symptoms getting worse. Do not stop taking Arthrix Capsules unless your doctor tells you to. Your doctor may want 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 listed below are observed at the higher frequencies that occurred in patients who took Celecoxib to prevent colon polyps. 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, or vomiting of blood
- a skin reaction such as rash, blistering or peeling of the skin
- liver failure (symptoms may include nausea (feeling sick), diarrhoea, abdominal pain, yellowing of the skin and eyes)
- very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

- Heart attack*
- Fluid built up with swollen ankles, legs and/or hands
- 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
- Muscle stiffness
- Difficulty swallowing*
- Nausea (feeling sick)
- Diarrhoea (runny stools)
- Worsening of existing allergies
- Accidental injury

Uncommon: may affect up to 1 in 100 people

- Stomach upset
- Heart failure, palpitations (irregular heart beat), fast heart rate
- Abnormalities in kidney-related blood tests
- Anaemia (changes in red blood cells that can cause fatigue and tiredness)
- 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, taste changes
- Constipation, burning, stomach inflammation (indigestion, stomach ache or vomiting), worsening of inflammation of the stomach or intestine
- Loss of appetite
- Raised itchy rash (hives)
- Eye inflammation
- Difficult breathing*
- Skin discolouration (bruising)
- Chest pain (generalised pain not related to the heart)

Rare: may affect up to 1 in 1,000 people

- Ulcers (bleeding) in the stomach, gut or intestines, or rupture of the stomach or intestines causing acute severe pain, vomiting, intestinal blockage, dark or black stools, inflammation of the pancreas (can lead to abdominal pain, diarrhoea, indigestion, nausea, vomiting)
- Low levels of calcium in the blood (a condition known as hypocalcaemia)
- Reduced number of white blood cells (which help to protect the body from infection) or blood platelets (increased chance of bleeding or bruising)
- Difficulty controlling muscular movements
- Fainting, pins and needles, changes in the way things taste
- Increased sensitivity to light
- Loss of taste
- Bleeding in the eye
- Acute reaction that may lead to lung inflammation
- Irritation of the heartbeats
- Flushing

Very rare: may affect up to 1 in 10,000 people

- Serious allergic reactions (including potentially fatal anaphylactic shock)
- Severe liver damage (including jaundice, Steven's Johnson syndrome, exfoliative dermatitis and toxic epidermal necrolysis) can cause pain, blisters or peeling of the skin (and acute generalised exanthematous pustulosis (AGEP))
- Soreness of the skin (erythema multiforme) becoming red with swollen areas covered in numerous small pustules

A delayed allergic reaction: possible symptoms such as rash, swelling of the face, mouth, tongue or throat, difficulty breathing or difficulty passing urine

Very rare: cannot be estimated from the available data

Decreased fertility in females: which is usually reversible on discontinuation of the medicine

In patients with osteoarthritis or with Arthrix or other arthritic 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: irritable bowel syndrome (can include stomach ache, diarrhoea, constipation, wind, bloating, cramps, abdominal pain)

Kidney stones: which may lead to stomach or back pain, blood in urine, difficulty passing urine

Very rare: cannot be estimated from the available data

Decreased fertility in females: which is usually reversible on discontinuation of the medicine

In patients with osteoarthritis or with Arthrix or other arthritic 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: irritable bowel syndrome (can include stomach ache, diarrhoea, constipation, wind, bloating, cramps, abdominal pain)

Kidney stones: which may lead to stomach or back pain, blood in urine, difficulty passing urine

Very rare: cannot be estimated from the available data

5. How to store Arthrix Capsules:

Keep Arthrix Capsules out of reach 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These medicines must not be disposed of in the environment.

6. Further Information

What Arthrix Capsules contain:

Each capsule contains Celecoxib 100 mg. Pg. Eur.

The other ingredients are: Lactose, Monohydrate, Croscarmellose sodium, Polyvinyl alcohol, Magnesium Stearate.

Arthrix Capsules 200 mg

Each capsule contains Celecoxib 200 mg. Pg. Eur.

The other ingredients are: Lactose, Monohydrate, Croscarmellose sodium, Polyvinyl alcohol, Magnesium Stearate.

Arthrix Capsules 100 mg

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 are supplied in blister pack.

Box of 10 blistered capsules (1x10's)

Box of 30 blistered capsules (3x10's)

How supplied:

Arthrix Capsules 100 mg

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 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 Medicament

- Medicament 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 number of doses to be taken, and do not exceed the recommended dose.

- The doctor or pharmacist is responsible for your health, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed by your doctor.

- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICAMENT OUT OF THE REACH OF CHILDREN

Source: National Health Ministers
Union of Arab Pharmacists

Manufactured by: neopharma

P.O. Box A-189-95, ICAD, Mussafah,

P.O. Box 72900, Abu Dhabi, UAE.

Arthrix is the Trademark of Neopharma

00200

July 2018
N. No. 23234

