

PATIENT INFORMATION LEAFLET

Arthrotec[®] 50 modified-release tablets diclofenac sodium, misoprostol

Read all of this leaflet carefully before you start taking this medicine

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor or pharmacist.**
- **This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.**
- **If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

In this leaflet:

1. **What Arthrotec is and what it is used for**
2. **Before you take Arthrotec**
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1. What Arthrotec is and what it is used for

Arthrotec helps to relieve the pain and swelling of **rheumatoid arthritis** and **osteoarthritis**, and may help to protect patients at risk of irritation or ulceration of the stomach or intestines.

Arthrotec contains diclofenac and misoprostol. Diclofenac belongs to a group of medicinal products called Non-Steroidal Anti-Inflammatory drugs (NSAIDs).

Although NSAIDs relieve the pain, they can reduce the amount of natural protective substances called prostaglandins in the stomach lining.

This means that NSAIDs can lead to stomach upsets or stomach ulcers. Arthrotec also contains misoprostol which is very similar to these prostaglandins and may help protect your stomach.

2. Before you take Arthrotec

Do not take Arthrotec

If you:

- have had an allergic reaction such as a skin rash, swelling or itchiness of the skin, severe nasal congestion, asthma or wheezing after taking diclofenac or other NSAIDs such as aspirin (acetylsalicylic acid), misoprostol or another prostaglandin medicine, or any of the other ingredients in Arthrotec (see Further Information section 6)
- currently have an ulcer or perforation (hole) in your stomach or intestines
- currently suffer from bleeding in your stomach, intestines or brain
- are undergoing or you have just had coronary artery bypass graft (CABG) surgery
- have severe kidney or liver failure
- have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- have or have had problems with your blood circulation (peripheral arterial disease)

- are pregnant, or trying to become pregnant, because it may cause a miscarriage. Women who have not reached the menopause should use reliable contraception while they are taking Arthrotec.

Take special care with Arthrotec

Make sure your doctor knows, before you are given Arthrotec

- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides

Check with your doctor if any of the following applies to you:

If you:

- have other health problems such as a disease of the liver or kidneys. **Do not take** Arthrotec if you have severe kidney or liver failure
- previously had an ulcer or bleeding in your stomach or intestines. **Do not take** Arthrotec if you currently have an ulcer or bleeding in your stomach or intestines
- bleed or bruise easily
- have inflammation of the intestines (ulcerative colitis or Crohn's disease)
- have, or have ever had asthma or an allergic disease
- have an infection, as Arthrotec may mask a fever or other signs of infection
- are dehydrated
- are over the age of 65 as your doctor may want to keep a regular check on you.

NSAID medicines such as Arthrotec can cause bleeding or ulceration. If this occurs, treatment should be stopped.

Medicines such as Arthrotec may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

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

If you have heart, liver or kidney problems, your doctor will want to monitor you regularly.

Taking other medicines

Some medicines can affect the way other medicines work. **Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines**, including medicines obtained without a prescription:

- Aspirin (acetylsalicylic acid) or other NSAIDs (e.g. ibuprofen)
- Medicines used to treat osteoarthritis or rheumatoid arthritis known as cyclo-oxygenase-2 (COX-2) inhibitors
- Diuretics (used to treat excess fluid in the body)
- Ciclosporin or tacrolimus (used for immune system suppression e.g. after transplants)
- Lithium (used to treat some types of depression)
- Digoxin (a medicine for an irregular heart beat and/or heart failure)
- Warfarin or other oral anticoagulants (blood-thinning agents that reduce blood clotting)
- Medicines used to treat anxiety and depression known as Serotonin Selective Re-uptake Inhibitors (SSRIs)

- Medicines used to control your blood sugar (oral hypoglycaemics for diabetes)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Steroid medications (e.g. corticosteroids, which are often used as anti-inflammatory medicines)
- Medicines for high blood pressure (anti-hypertensives)
- Magnesium containing antacids (used to treat heartburn, indigestion)
- Quinolone antibiotics (used to treat some infections)
- Ketoconazole (used to treat some fungal infections)
- If you have taken a medicine called mifepristone (used to terminate pregnancy) within the last 12 days. Arthrotec should not be taken within 8-12 days of taking mifepristone.

Pregnancy and breast-feeding

Do not use Arthrotec if you are pregnant or trying to become pregnant. Women who have not reached the menopause should use reliable contraception while they are taking Arthrotec.

Do not use Arthrotec while you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you feel dizzy or drowsy after taking Arthrotec, do not drive and do not use any tools or machines until these effects have worn off.

Important information about some ingredients of Arthrotec

Lactose or Sugar intolerance

Arthrotec contains **lactose** (a type of **sugar**). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Arthrotec.

3. How to take Arthrotec

Always take Arthrotec exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take one tablet two or three times a day, or as directed by your doctor.

Arthrotec should be swallowed whole with a drink of water (not chewed), taken during or after mealtimes.

In the elderly and patients with liver or kidney disorders, your doctor may want to monitor you more closely. No change in dose is needed.

Children: Arthrotec is for adults only, it is not for use in children (under 18 years).

If you take more Arthrotec than you should

You should not take more tablets than your doctor tells you to. If you take too many tablets contact your doctor, pharmacist or hospital as soon as possible, and take your medicine with you.

If you forget to take Arthrotec

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

If you stop taking Arthrotec

Do not stop taking Arthrotec unless your doctor tells you to. If you have any questions on the use of this product ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Arthrotec can have side effects, although not everybody gets them.

If you are worried about side effects, ask your doctor. It is important that you know what can happen, so that you can take action if Arthrotec does have a side effect. Arthrotec sometimes causes side effects but these usually go away during treatment as your body gets used to the medicine.

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

If you have

- severe stomach pain or any sign of bleeding or rupture in the stomach or intestines, such as passing black or bloodstained stools, or vomiting blood – this occurs **very rarely**
- a serious skin reaction such as rash, blistering or peeling of the skin (Stevens-Johnson syndrome, exfoliative dermatitis and toxic epidermal necrolysis) – this occurs **very rarely**
- a serious allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing (anaphylactic shock) – this occurs **rarely**
- jaundice (your skin or the whites of your eyes look yellow) – this occurs **rarely**
- Arthrotec can cause a decrease in a type of white blood cell (these help protect the body from infection and disease) and lead to infections with symptoms like chills, sudden fever, sore throat, or flu-like symptoms. Immediately contact your doctor if any of these symptoms develop – the frequency is **unknown**

Additionally, if any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- **Very common side effects**

(affecting more than 1 in every 10):

- Stomach ache, diarrhoea, nausea (feeling sick), indigestion

Diarrhoea is the most common problem and is occasionally severe. You have less chance of getting diarrhoea if you take Arthrotec with food. If you use an antacid (something to reduce acid in the stomach) you should avoid antacids with magnesium in them as these may make diarrhoea worse.

Your pharmacist can help you choose a suitable antacid. If this diarrhoea continues and is severe tell your doctor.

- **Common side effects**

(affecting less than 1 person in every 10, but more than 1 in every 100):

- Rash, itching
- Vomiting, wind, constipation, burping, gastritis (indigestion, stomach ache, vomiting)
- Ulcers in the stomach or intestines
- Headache, dizziness
- Difficulty sleeping
- Changes in blood tests relating to the liver

- **Uncommon side effects**

(affecting less than 1 person in every 100, but more than 1 in every 1000):

- Swelling of the mouth
- Abnormal or unexpected bleeding from the vagina, menstrual disturbances
- Reduction in the number of blood platelets (increased chance of bleeding or bruising)
- Purpura (purple spots on the skin)

- Urticaria (raised itchy rash)
- **Rare side effects**
(affecting less than 1 person in every 1,000, but more than 1 in every 10,000):
 - Inflammation of the liver (possible yellow discoloration of skin, headache, fever, chills, general weakness)
- **Very rare side effects**
(affecting less than 1 person in every 10,000 patients):
 - Severe liver disorders including liver failure
- **Additional side effects experienced in actual use**
(post-marketing experience, frequency unknown):
 - Heart failure, chest pain, palpitations (awareness of your heartbeat)
 - Damage to the gullet
 - Worsening of ulcerative colitis or Crohn's disease (inflammation of the intestines)
 - Kidney or liver problems
 - Shortness of breath
 - Seizures
 - Allergic reaction, (including asthma, breathing problems, itching, hair loss, inflamed blood vessels (can cause fever, aches, purple blotches))
 - Symptoms of meningitis (stiff neck, headache, nausea (feeling sick), vomiting, fever or loss of consciousness)
 - Fluid build-up in the body that can cause swollen ankles and legs
 - Vomiting blood
 - Psychotic reactions (mental disorder that features loss of contact with reality)
 - Swelling of the tongue, mouth ulcers, dry mouth
 - Depression, feeling anxious, mood swings, irritability, memory problems, feeling confused, feeling shaky, nightmares, drowsiness, tiredness
 - Difficulty seeing, impaired or blurred vision, ringing in the ears, changes in the way things taste
 - Chills, fever, increased sensitivity to light, inflammation
 - Loss of appetite
 - Abnormal contractions of the womb, rupture in the womb, retained placenta after giving birth, a life-threatening reaction in the mother due to the passage of amniotic fluid (fluid covering the fetus) or other foetal material into the maternal blood stream, bleeding in the womb, miscarriage, death of the unborn baby, birth defects, premature birth
 - Low blood pressure, high blood pressure
 - Anaemia (low number of red blood cells) which can lead to pale skin and cause weakness or breathlessness.

Medicines such as Arthrotec may be associated with a small increased risk of heart attack or stroke.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Arthrotec

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original packaging.

Do not use Arthrotec after the expiry date stated on the blister and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Arthrotec 50 contains

The active substances are diclofenac sodium and misoprostol.
One tablet contains 50 mg diclofenac sodium and 0.2 mg misoprostol.

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, corn starch, povidone, magnesium stearate, methylacrylic acid copolymer type C, sodium hydroxide, talc, triethylcitrate, hypromellose, crospovidone, hydrogenated castor oil and colloidal silicon dioxide.

What Arthrotec 50 looks like and contents of the pack

Arthrotec 50 is available as white, round, biconvex tablets, marked with four 'A's on one side, and 'Searle 1411' on the other side.

The tablets are packed in blister strips and supplied in boxes of 60 tablets.

Marketing Authorisation Holder

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Manufacturer

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