

Package leaflet: Information for the patient

Arthrotec® 50 modified-release tablets

diclofenac sodium, misoprostol

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.

What is in this leaflet

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

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. What you need to know before you take Arthrotec

Do not take Arthrotec

If you:

- think you may be allergic to diclofenac sodium, aspirin (acetylsalicylic acid), ibuprofen or any other NSAIDs, misoprostol or another prostaglandin medicine, or any of the other ingredients of Arthrotec (see section 6). Signs of a hypersensitivity reaction include a skin rash, swelling or itchiness of the skin, swelling of the face and mouth (angioedema), severe nasal congestion, asthma (breathing problems), chest pain, wheezing or any other allergic type reaction.
- 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
- are a woman of childbearing age and you are not using an effective contraceptive method to avoid becoming pregnant (see section on 'Pregnancy' for further information)

Warnings and precautions

Talk to your doctor or pharmacist before taking Arthrotec

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
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Arthrotec or other pain medications
- are dehydrated
- are over the age of 65 as your doctor will want to monitor you regularly
- are pregnant or plan to become pregnant (see section on "Pregnancy"). Due to the risk to the foetus, your treatment with Arthrotec must be discontinued immediately
- are a woman of childbearing age (see also section on "Pregnancy"). It is important to use effective contraception while you are taking this medicine
- recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using Arthrotec, as Arthrotec can sometimes worsen wound healing in your gut after surgery

NSAID medicines such as Arthrotec can cause bleeding or ulceration. If this occurs, treatment should be stopped. Use of Arthrotec with another NSAID other than aspirin (e.g. ibuprofen) may also increase frequency of ulcers or bleeding in your stomach or intestines.

Arthrotec may cause serious side effects, especially stomach and intestinal complications, if you are using a corticosteroid (e.g. prednisone), an oral anticoagulant, or a Selective Serotonin Re-uptake Inhibitor (e.g. sertraline) or if you drink alcohol.

Make sure your doctor knows, before you are given Arthrotec

If you:

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

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.

Other medicines and Arthrotec

Some medicines can affect the way other medicines work. **Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines,** including:

- Aspirin (acetylsalicylic acid) or other NSAIDs (e.g. ibuprofen)
- Medicines used to treat osteoarthritis or rheumatoid arthritis known as cyclooxygenase-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, e.g. aspirin)
- Medicines used to treat anxiety and depression known as Selective Serotonin 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, fluconazole, miconazole and voriconazole (used to treat some fungal infections)
- Amiodarone (used to treat an abnormal heart beat)
- Sulfapyridazole (used to treat gout)
- 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, breast-feeding and fertility

Pregnancy

Do not take Arthrotec if you are pregnant, think you may be pregnant or trying to become pregnant. You should tell your doctor if you are planning to become pregnant. Due to the possible risk of damage to the foetus, you must make sure you are not pregnant before starting treatment. Women who have not reached menopause must use reliable contraception while they are taking Arthrotec.

Your doctor will make you aware of the risks if you do become pregnant while taking Arthrotec as it may cause a miscarriage, premature birth, abnormal formation of the foetus (birth defects). You should NEVER take this medicine if you are pregnant, as it can also have severe consequences on your child, especially on the heart, lungs and/or kidneys, including death. If you have received treatment with this medicine during pregnancy, talk with your doctor. If you decide to continue with the pregnancy, careful ultrasound scan monitoring of the pregnancy, with special attention to the limbs and head must be carried out.

Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine if you are breast-feeding. Do not use Arthrotec while you are breast-feeding.

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.

Arthrotec contains Lactose

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.

Arthrotec contains Sodium

Arthrotec also contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Arthrotec contains hydrogenated castor oil

Arthrotec contains hydrogenated castor oil, which may cause stomach upset and diarrhoea.

3. How to take Arthrotec

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet two or three times a day, 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.

Use in 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 a forgotten dose.

If you stop taking Arthrotec

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

4. Possible side effects

Like all medicines, this medicine can cause 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**

- Weakness of or inability to move one side of body, slurred speech (stroke) or chest pain (heart attack) or heart failure or palpitations (awareness of your heartbeat) – the occurrence is **uncommon**
- Shortness of breath – the occurrence is **uncommon**
- 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 – the occurrence is **uncommon**
- Severe stomach pain or any sign of bleeding or rupture in the stomach or intestines, such as passing black or bloodstained stools – the occurrence is **uncommon**, or vomiting blood – this occurs **rarely**
- A serious allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing (anaphylactic shock), or swelling under the skin (angioedema) – this occurs **rarely**
- A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching (Generalised bullous fixed drug eruption)
- Jaundice (your skin or the whites of your eyes look yellow) – this occurs **rarely**
- Reduction in the number of blood platelets (increased chance of bleeding or bruising) – it is not known how often this occurs
- Symptoms of meningitis (stiff neck, headache, nausea (feeling sick), vomiting, fever or loss of consciousness) – it is not known how often this occurs
- A serious skin reaction such as rash, blistering or peeling of the skin (DRESS syndrome, Stevens-Johnson syndrome, exfoliative dermatitis, erythema multiforme, and toxic epidermal necrolysis) – it is not known how often this occurs
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome - it is not known how often this occurs

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

- **Very common: may affect more than 1 in 10 people**
 - 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: may affect up to 1 in 10 people**
 - 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
 - Inflammation of the digestive tract, including the intestines, such as nausea, diarrhoea, abdominal pain
 - Abnormal formation of foetus
 - Low number of red blood cells in blood tests (haematocrit decreased)
- **Uncommon: may affect up to 1 in 100 people**
 - Swelling of the mouth
 - Swelling of the face
 - Fluid build-up in the body that can cause swollen ankles and legs
 - 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)
 - Infection of the vagina (itching, burning, soreness, pain especially during intercourse and/or urination)
 - Blurred vision
 - High blood pressure
 - Loss of appetite
 - Menstrual disorders such as usually heavy or light bleeding, or delayed periods
 - Chills or fever
 - Drowsiness, tiredness, feeling shaky
 - Ringing in the ears
 - Depression and feeling anxious
 - Tingling or pricking (pins and needles)
 - Mouth ulcers and dry mouth
- **Rare: may affect up to 1 in 1,000 people**
 - Inflammation of the liver (possible yellow discoloration of skin, headache, fever, chills, general weakness)
 - Inflammation of the pancreas, which causes severe pain in the abdomen and back
 - Inflammation of the lung such as coughing, increased sputum
 - Breast pain
 - Vomiting blood
 - Worsening of ulcerative colitis (inflammation of lower intestine)
 - Damage to the gullet
 - Low blood pressure
 - Hair loss
 - Increased sensitivity to light
 - Nightmares
 - Blistering of the skin (dermatitis bullous)
 - Painful menstrual/period cramps
- **Very rare: may affect up to 1 in 10,000 people**
 - Severe liver disorders including liver failure

- **Not known: frequency cannot be estimated from the available data**
 - Worsening of Crohn's disease (inflammation of the intestines)
 - Kidney problems
 - Seizures
 - Inflamed blood vessels (can cause fever, aches, purple blotches)
 - Psychotic disorder (mental disorder that features loss of contact with reality)
 - Mood swings, irritability, memory problems, feeling confused
 - Difficulty seeing, changes in the way things taste
 - Inflammation

- 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 fetal material into the maternal blood stream, bleeding in the womb, miscarriage, death of the unborn baby, premature birth
- Abnormal bleeding in the womb
- Anaemia (low number of red blood cells) which can lead to pale skin and cause weakness or breathlessness
- Decreased fertility in females
- Asthma (breathing problems)
- Swelling of the tongue
- Steep fall in blood pressure
- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arthrotec

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C

Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry which is stated on the carton and blister after EXP or Scadenza. 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 measures will help protect the environment.

6. Contents of the pack and other information

What Arthrotec 50 contains

The active substances are diclofenac sodium and misoprostol.

Each tablet contains 50 mg diclofenac sodium and 200 micrograms misoprostol.

The other ingredients are:

Product imported from Spain contains lactose, microcrystalline cellulose, maize starch, povidone, cellulose acetate phthalate, diethyl phthalate, hypromellose, crospovidone, magnesium stearate, hydrogenated castor oil, colloidal anhydrous silica.

Product imported from France contains lactose, microcrystalline cellulose, maize starch, povidone, magnesium stearate, methacrylic acid copolymer type C, sodium Hydroxide, talc, triethyl citrate, crospovidone, colloidal anhydrous silica, hydrogenated castor oil.

Product imported from Netherlands contains lactose monohydrate, microcrystalline cellulose, maize starch, povidone K-30, hypromellose, crospovidone, magnesium stearate, methylacrylic acid copolymer type-C, sodium hydroxide, talc, triethyl citrate, hydrogenated castor oil, colloidal silicon dioxide,

What Arthrotec looks like and contents of the pack

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

Pack size: Arthrotec is available in blister packs of 40 or 60 tablets. Not all pack sizes may be marketed.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Piramal Pharma Solutions (Dutch) B.V. , Level, 7e verdieping, Bargelaan 200, 2333 CW, Leiden, Netherlands

Parallel Product Authorisation Number

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Arthrotec is a registered trademark of Wyeth Holdings LLC

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