

ARTHROTEC® 50

(arth-row-tech)

Diclofenac Sodium/Misoprostol (dic-low-fen-ack me-so-pros-tal)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Arthrotec 50.

It does not contain all the available information. 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 Arthrotec 50 against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Arthrotec 50 is used for

What Arthrotec 50 does

This medicine is used to relieve joint pain, tenderness, swelling and stiffness that may occur in osteoarthritis and rheumatoid arthritis, whilst protecting your stomach.

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

How Arthrotec 50 works

This medicine contains two active ingredients: diclofenac sodium and misoprostol.

Diclofenac sodium belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines work by relieving pain and inflammation. However, this kind of arthritis medicine can sometimes irritate the stomach or cause ulcers because it reduces the amount of natural protective substances (called prostaglandins) in the stomach lining.

Misoprostol is very similar to these natural prostaglandins and can help protect the stomach. Arthrotec 50 therefore helps protect your stomach while you continue to receive the benefit from the anti-arthritis medicine.

Taking Arthrotec 50

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Use in children

There is not enough information to recommend the use of this medicine in children under the age of 18 years.

Before you take Arthrotec 50

When you must not take it

Do not take Arthrotec 50 if you have an allergy to:

- any medicine containing diclofenac sodium or misoprostol
- any of the ingredients listed at the end of this leaflet
- aspirin
- any other NSAID medicine
- any medicine that is a COX-2 inhibitor
- prostaglandins.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- asthma
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- fainting.

If you are allergic to aspirin, NSAIDs or COX-2 inhibitors and take this medicine, these symptoms may be severe.

Do not take Arthrotec 50 if you have or have had any of the following medical conditions:

- a peptic ulcer i.e. stomach or duodenal ulcer
- bleeding in your stomach; this may be indicated by black sticky bowel motions (stools) or if you are vomiting blood.

Do not take this medicine if you are pregnant, if there is a possibility you may be pregnant, or if you intend to become pregnant.

Use of NSAIDs in early pregnancy can increase the risk of spontaneous abortion.

This medicine may also cause a miscarriage, leading to dangerous bleeding, infertility or death.

Pregnant women taking ARTHROTEC should be closely monitored by their doctor. One of the active ingredients in Arthrotec 50 may have harmful effects on a developing baby (fetus). This medicine may also cause a problem in the blood vessels of the developing baby and it may affect labour.

Women who are capable of falling pregnant must use adequate contraception while taking Arthrotec 50. Examples of adequate contraception are oral contraceptives ("the pill") or intra-uterine devices (IUDs).

NSAIDs have been associated with reversible infertility in some women.

Do not take Arthrotec 50 if you are breast-feeding or intend to breast-feed.

One of the active ingredients in this medicine passes into breast milk, therefore it is not recommended that you take this medicine if you are breastfeeding.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If you take this medicine after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor or pharmacist if you have any allergies to:

- any other medicines including aspirin or other NSAID medicines

- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- liver or kidney problems
- diabetes
- seizures or fits (epilepsy)
- asthma
- high blood pressure or heart failure.
- heart disease, Use of ARTHROTEC may increase your risk of developing cardiovascular events (e.g. heart attack) even if you don't have a history of heart disease.
- diseases of your blood vessels
- peptic ulcer i.e. stomach ulcer or duodenal ulcer
- vomiting blood or material that looks like coffee grounds
- bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.

Tell your doctor or pharmacist if:

- you are pregnant
- you are breastfeeding.

Arthrotec 50 must not be used during pregnancy or breastfeeding.

Tell your doctor or pharmacist if you currently have an infection.

If you take Arthrotec 50 while you have an infection, it may hide some of the signs of an infection. An infection may include, but is not limited to, coughing, sneezing, pain, nausea or vomiting.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking Arthrotec 50.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.
- alcohol

Some medicines may be affected by Arthrotec 50 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Tell your doctor or pharmacist if you are taking medicines for any of the following medical conditions:

- inflammation or pain - especially aspirin, salicylates or other NSAID medicines or corticosteroids
- stomach problems - especially antacids
- blood clots (thrombosis) - especially Plavix or warfarin or similar medicines such as Eliquis, Xarelto or Pradaxa
- heart failure - especially digoxin
- depression - especially lithium or selective serotonin reuptake inhibitors

- high blood pressure
- swelling - especially diuretics, also called fluid or water tablets
- diabetes - especially insulin
- fungal infections - especially voriconazole
- gout - especially sulfinpyrazone
- arthritis and some cancers - especially methotrexate
- organ transplantation or immune system problems - especially cyclosporin.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking this medicine.

How to take Arthrotec 50

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

The usual dose of Arthrotec 50 is one tablet taken 2 or 3 times a day.

How to take it

Arthrotec 50 is best taken with food. Swallow the tablets whole with a full glass of water. Do not chew or crush them.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Arthrotec 50 is best taken with food.

How long to take it

Depending on your arthritis condition, you may need to take Arthrotec 50 for a few weeks or longer. This medicine will not cure your condition but it should help to control arthritic pain, swelling and stiffness.

Keep taking Arthrotec 50 for as long as your doctor advises.

If you need to take Arthrotec 50 for a long time, see your doctor for regular check-ups so that he/she can monitor your condition and treatment. This includes periodic liver testing if you take Arthrotec 50 for 8 weeks or more.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Arthrotec 50.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include sedation, drowsiness, confusion, shaking, fits, shortness of breath, stomach pains, diarrhoea, fever, heart palpitations, slow heartbeat, low blood pressure, or general weakness.

While you are taking Arthrotec 50

Things you must do

If you suspect you may be pregnant, stop taking Arthrotec 50 immediately and tell your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Arthrotec 50.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may periodically test your liver function if you take this medicine for 8 weeks or more.

Things you must not do

Do not take Arthrotec 50 to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful of ingesting alcohol whilst taking ARTHROTEC. As with other NSAIDs medicines ingesting alcohol may increase your risk of developing stomach problems.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Arthrotec 50.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some side effects.

It can be difficult to tell whether side effects are the result of taking Arthrotec 50, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if...

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

- stomach pains, diarrhoea, constipation, indigestion, wind, burping
- swollen hands, ankles and feet
- unexplained weight gain
- dizziness or nausea
- headache
- vomiting
- menstrual problems
- liver or kidney problems
- mouth ulcers or cold sores.

If stomach pains or diarrhoea occur, they usually settle down after 2-3 days. If you take Arthrotec 50 with food you will have less chance of getting diarrhoea (or it will be less severe if you do get it).

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

- changes in mood.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following.

- collapse or fainting
- shortness of breath, weakness and tiredness
- chest pain
- nausea, vomiting, palpitations, indigestion, sweating or anxiety (these may be symptoms of a heart attack)
- swollen or sore leg veins
- severe pain or tenderness in the stomach, vomiting blood or black sticky bowel motions
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- nausea, vomiting, itchiness, flu-like symptoms, loss of appetite, feeling generally unwell, or yellowing of the skin or eyes (jaundice)
- severe dizziness, spinning sensation
- severe or persistent headache
- trouble with walking, speaking or understanding, paralysis or numbness on one side of the face or body, a sudden stabbing headache with or without vomiting, or trouble with seeing including double vision (these may be symptoms of a stroke)
- fast or irregular heartbeats, also called palpitations
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash.

Not all of these side effects have been reported with Arthrotec 50 but may have been seen with similar medicines.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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After taking Arthrotec 50

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Arthrotec 50 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Arthrotec 50 tablets are white, round, biconvex (curves outward on both sides) tablets marked with four 'A's on one side and SEARLE 1411 on the other side.

Arthrotec 50 comes in blister packs of 60 tablets.

Ingredients

Each Arthrotec 50 tablet contains 50 milligrams of diclofenac sodium and 200 micrograms of misoprostol as the active ingredients.

Other ingredients in each tablet are:

- hypromellose
- lactose monohydrate
- microcrystalline cellulose
- maize starch
- povidone K-30
- magnesium stearate
- methacrylic acid copolymer
- sodium hydroxide
- triethyl citrate
- crospovidone
- colloidal anhydrous silica
- hydrogenated castor oil
- talc.

This medicine does not contain sucrose, tartrazine or any other azo dyes.

Supplier

Arthrotec 50 is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde, NSW 2114

Toll Free Number: 1800 675 229

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