

ARTHROTEC(R) 50

Diclofenac Sodium/Misoprostol

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.

Read this leaflet carefully before you start taking ARTHROTEC 50. Keep this leaflet with the medicine.

You may need to read it again.

What ARTHROTEC 50 is used for

ARTHROTEC 50 is used to relieve joint pain, tenderness, swelling and stiffness that may occur in osteoarthritis and rheumatoid arthritis, whilst protecting your stomach.

Although ARTHROTEC 50 can relieve the symptoms of pain and inflammation, it will not cure your condition.

ARTHROTEC 50 contains 2 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.

Your doctor may have prescribed ARTHROTEC 50 for another purpose. Ask your doctor if you have any questions about why ARTHROTEC 50 has been prescribed for you.

ARTHROTEC 50 has not been studied in children less than 18 years of age.

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

Before you take ARTHROTEC 50

When you must not take it

Do not use ARTHROTEC 50 if:

1. you have an allergy to:

- * ARTHROTEC 50 or any of the ingredients listed at the end of this leaflet
- * aspirin

- * any other NSAID medicine
- * 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.

Symptoms of an allergic reaction to these medicines may include:

- * asthma, wheezing or shortness of breath
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- * hives, itching or skin rash
- * fainting

If you are allergic to aspirin or NSAID medicines and take ARTHROTEC 50, these symptoms may be severe.

2. you are pregnant or there is a possibility you may be pregnant, or if you intend to become pregnant.

ARTHROTEC 50 MAY CAUSE A MISCARRIAGE, LEADING TO DANGEROUS BLEEDING, INFERTILITY OR DEATH.

One of the active ingredients in ARTHROTEC 50 may have harmful effects on a developing baby (fetus). ARTHROTEC 50 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).

3. you are breast-feeding or intend to breast-feed.

One of the active ingredients in ARTHROTEC 50 passes into breast milk, therefore it is not recommended that you take ARTHROTEC 50 if you are breastfeeding.

4. you have a peptic ulcer (ie stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.

5. you have bleeding in your stomach.

6. the packaging is torn or shows signs of tampering.

7. the expiry date (EXP) printed on the pack has passed.

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

If you are not sure whether you should start taking ARTHROTEC 50, contact your doctor.

Before you start to take it

Tell your doctor if:

1. you have any allergies to:

- * any other medicines including aspirin or other NSAID medicines
- * any other substances, such as foods, preservatives or dyes

2. you have any other medical problems including:

- * liver or kidney problems
- * diabetes
- * seizures or fits (epilepsy)
- * asthma
- * high blood pressure or heart failure
- * diseases of your blood vessels
- * peptic ulcer (ie. stomach ulcer or duodenal ulcer), a recent history of peptic ulcer, or if you have had peptic ulcers before
- * vomiting blood or material that looks like coffee grounds
- * bleeding from the rectum (back passage), have black sticky bowel

motions (stools) or bloody diarrhoea.

3. you are pregnant or intend to become pregnant

ARTHROTEC 50 should not be used during pregnancy.

4. you are breast-feeding or plan to breast-feed.

Like most NSAID medicines, ARTHROTEC 50 is not recommended while you are breast-feeding. One of the ingredients in ARTHROTEC 50 passes into breast milk and therefore there is a possibility that a breast-fed baby may be affected.

5. 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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ARTHROTEC 50. These include:

- * aspirin, salicylates or other NSAID medicines
- * antacids
- * warfarin, a medicine used to stop blood clots (thrombosis)
- * digoxin, a medicine used to treat heart failure
- * lithium, a medicine used to treat some types of depression
- * medicines used to treat high blood pressure
- * diuretics, also called fluid or water tablets
- * medicines used to treat diabetes such as insulin
- * methotrexate, a medicine used to treat arthritis and some cancers
- * cyclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system

These medicines may be affected by ARTHROTEC 50, or may affect how well it works. Your doctor may need to adjust the dosage of these medicines, or provide additional advice if you are taking ARTHROTEC 50.

How to take ARTHROTEC 50

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

They may differ from the information contained in this leaflet.

How much to take

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 ARTHROTEC 50 tablets whole. Do not chew them.

How long to take it

Depending on your arthritis condition, you may need to take ARTHROTEC 50 for a few weeks or longer. ARTHROTEC 50 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 take ARTHROTEC 50 for 8 weeks or more your doctor should periodically test your liver function.

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 tablets as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that 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. Keep these telephone numbers handy.

If you take too much ARTHROTEC 50, you may notice sedation, drowsiness, confusion, shaking, fits, shortness of breath, stomach pains, diarrhoea, fever, heart palpitations, slow heart beat, low blood pressure, or general weakness.

While you are using 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 start taking any new medicine tell your doctor and pharmacist that you are taking ARTHROTEC 50.

Tell all of the doctors, dentists, and pharmacists that are treating you that you are taking ARTHROTEC 50.

If you are going to have surgery, tell your doctor you are taking ARTHROTEC 50.

Things you must not do

Do not give ARTHROTEC 50 to anyone else, even if they have the same condition as you.

Do not use ARTHROTEC 50 to treat any other complaints unless your doctor tells you to.

Side effects

Check with your doctor as soon as possible if you have any problems while taking ARTHROTEC 50, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, ARTHROTEC 50 can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Tell your doctor if you notice any of the following:

- * 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
- * changes in mood
- * 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 immediately if you notice any of the following:

- * Collapse or fainting, shortness of breath or tiredness, chest pain, 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
- * 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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using ARTHROTEC 50

Storage

Keep the tablets in a cool dry place where the temperature stays below 25 degrees C. Do not store ARTHROTEC 50 or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

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 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 ARTHROTEC 50 or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

This document was revised in July 2005.

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Product description

What it looks like

ARTHROTEC 50 Tablets are white, round, biconvex 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, microcrystalline cellulose, maize starch, povidone K-30, magnesium stearate, cellucephate, diethyl phthalate, crospovidone, colloidal anhydrous silica, hydrogenated castor oil, talc.

ARTHROTEC 50 does not contain sucrose, tartrazine or any other azo dyes.

Manufacturer/Distributor/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

Australia

Australian Registration Number:

AUST R 63062