ARTRODAR® 50 mg

Consumer Medication Information Leaflet (RiMUP)

Diacerein (50 mg)

What is in this leaflet

What ARTRODAR is used for

ARTRODAR contains the active substance diacerein and is used to relieve symptoms of osteoarthritis of the hip or knee.
It takes some time for ARTRODAR to have its effect. Treatment with ARTRODAR is therefore not recommended for a specific form of hip osteoarthritis called rapidly progressive (worsening) hip osteoarthritis. Patients with such form of the disease may derive less benefit from treatment.

How ARTRODAR works

ARTRODAR has anti- inflammatory properties and can decrease pain, improve joint function and reduce cartilage destruction in osteoarthritis patients.

Before you use ARTRODAR

When you must not use it

Do not use ARTRODAR

- if you are allergic to diacerein or any of the other ingredients of this medicine
- if you have any liver problems or a history of liver problems
- if you suffer from certain diseases of the intestine called ulcerative colitis or Crohn disease
- if you suffer from intestinal obstruction or pseudo-obstruction.
- if you have abdominal disorders, for which the cause is not defined
- in children
- if you are pregnant or breast-feeding.

Before you start to use it

Talk to your doctor or pharmacist before taking ARTRODAR if you have ever suffered from liver disease.

Some patients may experience loose stools or diarrhoea after the intake of ARTRODAR. If you have diarrhoea while taking this medicine, stop taking ARTRODAR and contact your doctor to discuss which other treatments you can take.

ARTRODAR is not recommended in patients over 65 years of age, as this category of patients is more vulnerable to complications associated with severe diarrhoea. In the case of treatment with ARTRODAR, no change in the recommended dosage is required. However, caution should be exercised. If diarrhoea does occur, discontinue treatment and consult your doctor.

You should not take laxatives during your treatment with ARTRODAR.

Liver problems including raised liver enzymes in the blood and hepatitis (inflammation in the liver) have been reported in some patients taking diacerein. Your doctor may ask you to undergo blood tests to check your liver function.

Drinking alcohol while taking ARTRODAR may increase the risk of liver damage. You should limit your alcohol consumption while you are undergoing treatment with ARTRODAR.

You should not take ARTRODAR if you are pregnant or breast-feeding or if you think you may be pregnant or are planning to have a baby, as insufficient data are available on the use of diacerein during pregnancy.

No effects on the capacity to drive or to operate machines are known, as no studies have been performed on this subject.

ARTRODAR contains lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking ARTRODAR.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some antacids (medicines for treating stomach acidity) should not be taken together with ARTRODAR, as they reduce the body's ability to absorb ARTRODAR; there should be a minimum interval of two hours between taking an antacid and taking ARTRODAR.

The intake of ARTRODAR can provoke diarrhoea, which may lead to a loss of potassium. If you take a diuretic or cardiac glycosides (digitoxin, digoxin) at the same time, the risk of heart rhythm disorders (arrhythmia) can be increased.

How to use ARTRODAR

How much to use

It is recommended that you start treatment with one capsule in the evening for the first 2-4 weeks, after which the dose can be increased to two capsules per day.

When to use it

Take ARTRODAR with food, one with breakfast and the other with the evening meal. Swallow the capsules intact, without opening them, with a glass of water.

How long to use it

Although it takes some time for ARTRODAR to have its effect, the effect persists after the end of the treatment. Due to the delayed onset of its activity, even if you do not experience a relief of your symptoms when you first begin to use it, you should take ARTRODAR continuously for a minimum period of one month in order to allow the medicine develop its full beneficial effects.

During the first 2-4 weeks of treatment, if necessary, your doctor may additionally prescribe a painkiller or an anti-inflammatory drug for you to obtain a faster improvement of your symptoms.

Your doctor will decide the duration of treatment as a function of the outcome. When symptoms reappear, your doctor may decide to repeat the treatment with ARTRODAR.

If you forget to use it

Do not take a double dose to make up for forgotten individual doses. Continue the treatment with your normal dose at the usual time.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you use too much (overdose)

If you take more ARTRODAR than you should (overdose), this may cause intense diarrhoea; in this case, drink sufficient fluid and see your doctor. Bring the remaining capsules or the packaging and show them to your doctor, so that he/she is informed about the medicine that you have taken.

While you are using it

Things you must do

Tell your doctor immediately and stop taking ARTRODAR if you experience unusually frequent liquid or watery stools.

Tell your doctor immediately if you have abdominal pain, jaundice (yellow discolouration of the eyes or skin), impaired consciousness or itching of the skin, as these may indicate serious conditions such as liver disease.

Things you must not do

Do not give ARTRODAR to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Your urine may turn reddish or brownish in colour; this discolouration is harmless and is due to the presence of degradation products of ARTRODAR in the urine. However, if you suspect that there could be traces of blood, you should see your doctor. Because of this discolouration, some urine diagnostic tests can be biased (for example,
urine sugar dipstick tests). If you are uncertain concerning the interpretation of your urine test, please ask your doctor.

If you have moderate kidney function impairment, no change to the usual recommended dose is necessary. However, if you have severe kidney disease, talk to your doctor, as he/she may ask for a medical examination as a precaution and kidney function tests would be carried out periodically. In addition, your doctor may reduce your daily dose of diacerein by half.

Side effects

Like all medicines, ARTRODAR can cause side effects, although not everybody gets them. Please inform your doctor or pharmacist if one of the side effects listed below constitutes a significant impairment for you or if you notice any side effects not mentioned in this leaflet.
The following side effects were observed in patients treated with diacerein:

Very common side effects (may affect more than 1 in 10 people treated):

- diarrhoea
- abdominal pain
- discolouration of your urine.

In some cases, diarrhoea can be severe with life threatening complications such as fluid loss and electrolyte disturbances.

Common side effects (may affect up to 1 in 10 people treated):

- frequent bowel movements
- soft stools
- flatulence
- pruritus (itching), rash, eczema (itchy, red rash).

Uncommon side effects (may affect up to 1 in 100 people treated):

- increase in liver enzymes levels in blood tests
- discolouration of colon mucosa (observed during colonoscopy).

Compared to many painkillers from the group 'non-steroidal anti-inflammatory drugs' (NSAIDs), diacerein showed good gastric tolerance. Mucosal inflammation and ulcers in the gastrointestinal tract do not occur during treatment with diacerein.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my *[Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]*.

Storage and Disposal of ARTRODAR

Storage

Keep this medicine out of the sight and reach of children.
Do not store above 30 °C. Store in the original package.

Disposal

Do not use this medicine after the expiry date which is stated on the carton.

Product Description

What it looks like

ARTRODAR is sold in the form of capsules. Each capsule has a white opaque body with a green opaque cap.

ARTRODAR is available in blisters packed in boxes containing 30 capsules.

Ingredients

The active ingredient is diacerein. Each capsule contains 50 mg diacerein.

The inactive ingredients are:

Capsule content:
lactose monohydrate (214.3 mg), croscarmellose sodium, povidone, colloidal silicon dioxide, magnesium stearate.

Capsule:
gelatin, yellow iron oxide (E 172), FD & C Blue No. 2 (E 132), titanium dioxide (E 171).

MAL number: MAL20041211AZ

Manufacturer

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Product Registration Holder

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