

APO-DICLO SR TABLETS

Contains the active ingredient diclofenac sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Apo-Diclo SR. 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 Apo-Diclo SR against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What this medicine is used for

Diclofenac SR is used for the treatment of:

- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, nonarticular rheumatism.
- Post-traumatic and post-operative pain, inflammation, and swelling, e.g. following dental or orthopaedic surgery.
- Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis.

Diclofenac SR belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

These medicines can relieve the symptoms of pain and inflammation, but they will not cure your condition.

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

Your doctor may have prescribed it for another reason.

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

This medicine is not addictive.

Use in children

This is not recommended for use in children, as there is not enough information on its use in this age group.

Before you take this medicine

When you must not take it

Do not take diclofenac if you are allergic to:

- diclofenac
- other medicines containing diclofenac
- aspirin/acetylsalicylic acid
- any other NSAID medicine
- any of the ingredients listed at the end of this leaflet.

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 may include asthma, shortness of

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

If you are allergic to aspirin or NSAID medicines and take Apo-Diclo SR, these symptoms may be severe.

Do not take diclofenac if at the present time you have an ulcer (gastric or duodenal) or bleeding from the stomach or bowel. If you take it, your stomach problem may become worse.

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

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 if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any other health problems, including:

- ulcers (gastric or duodenal)
- severe attacks of indigestion or other stomach trouble
- diseases of the bowel (e.g. Crohn's disease, ulcerative colitis)
- bleeding from your rectum (back passage)
- established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart

disease, or peripheral arterial disease), as treatment with Apo-Diclo SR is generally not recommended.

- established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke and your doctor decides to prescribe Apo-Diclo SR, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- it is generally important to take the lowest dose of Apo-Diclo SR that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.
- kidney disease
- liver disease
- a tendency to bleed or other blood problems such as anaemia
- asthma
- haemorrhoids (piles) or irritation of the rectum (back passage)

Tell your doctor if you have an infection at the present time.

If you take Apo-Diclo SR while you have an infection, some of the signs of the infection may be hidden (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that the infection is not serious.

Tell your doctor if you are pregnant or are breast-feeding.

Like most NSAID medicines, Apo-Diclo SR is not recommended for use during pregnancy or breast-feeding. Your doctor will discuss with you the benefits and risks of taking it.

If you have not told your doctor about any of the above, tell them before you start taking diclofenac.

Taking other medicines

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

Some medicines may interfere with diclofenac or increase the risk of side effects. These include:

- aspirin, salicylates, ibuprofen, or other NSAID medicines
- warfarin, a medicine used to stop blood clots
- digoxin, a medicine for your heart
- lithium, a medicine used to treat some types of depression
- diuretics, also called fluid or water tablets
- tablets used to treat diabetes (such as metformin)
- methotrexate, a medicine used to treat arthritis and some cancers
- cyclosporin, tacrolimus, medicines used to suppress the immune system
- trimethoprim, a medicine used to prevent or treat urinary tract infections
- certain antibiotics called quinolones
- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure and heart failure)
- corticosteroids (medicines used to provide relief for inflamed areas of the body)
- sulfapyrazone (a medicine used to treat gout)
- phenytoin (a medicine used to treat seizures).
- Rifampicin (an antibiotic medicine used to treat bacterial infections)

These medicines may be affected by diclofenac 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 has more information on medicines to be careful with or to avoid while taking diclofenac.

How to take this medicine

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 pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will assess your situation and the lowest effective dose for the shortest possible duration will be prescribed.

Adults:

For moderate to severe acute pain: Daily doses of 100mg to 150mg administered as either one 75mg tablet twice daily or one 100mg tablet once daily.

For mild to moderate acute pain or long term chronic pain relief: either one 75mg tablet or one 100mg tablet once daily.

If symptoms are most pronounced during the night or in the morning, the tablets should be taken in the evening.

Children:

Apo-Diclo SR is not suitable for children because of its dosage strength.

Elderly:

Dosage should be minimised, and close monitoring is recommended.

Use in Impaired Renal Function:

Dosage reductions may be necessary when creatinine clearance is <10mL/min. In all cases of renal dysfunction, frequent monitoring is required.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets whole with a full glass of water. Do not chew them.

The tablets have a special coating to stop them dissolving until they have passed through the stomach into the bowel. Chewing them would destroy the coating.

If long-term therapy is anticipated or the patient has a history of gastrointestinal ulceration, it is advisable to take tablets with or after food to lessen the risk of duodenal ulceration.

When to take it

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

Apo-Diclo SR will work more quickly if you take it with meals.

How long to take it for

Do not take Apo-Diclo SR for longer than your doctor says.

If you are taking Apo-Diclo SR for arthritis, it will not cure your disease but it should help to control pain and inflammation. It usually begins to work within a few hours but several weeks may pass before you feel the full effects of the medicine.

For menstrual cramps (period pain), the tablets are usually taken during each period as soon as cramps begin and continued for a few days until the pain goes away.

If you take Apo-Diclo SR for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.

If you have questions about how long to take Apo-Diclo SR, talk to your doctor or your pharmacist.

If you forget to take it

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take the next dose when you are meant to.

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

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone in Australia - 13 11 26; in New Zealand - 0800 POISONS or 0800 764 766) for advice if you think that you or anyone else may have taken too much diclofenac.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

If you become pregnant while taking Apo-Diclo SR, tell your doctor immediately. Your doctor can discuss with you the risks of taking it while you are pregnant.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Apo-Diclo SR.

Take Apo-Diclo SR exactly as your doctor has prescribed. If you do not follow your doctor's instructions, your condition may not improve, or you may have unwanted side effects.

If, for any reason, you have not taken your medicine exactly as prescribed, tell your doctor. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

If you feel the medicine is not helping, tell your doctor. This will help your doctor to determine the best treatment for you.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

If you have established heart disease or significant risks for heart disease, make sure to tell your doctor. Your doctor will periodically re-evaluate whether you should continue treatment with Apo-

Diclo SR, especially in case you are treated for more than 4 weeks.

If, at any time while taking Apo-Diclo SR you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

If you are going to have surgery, make sure the surgeon and anaesthetist know that you are taking Apo-Diclo SR. NSAID medicines can slow down blood clotting.

If you get an infection while taking Apo-Diclo SR, tell your doctor. This medicine may hide some of the signs of an infection (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that the infection is not serious.

Tell all of the doctors, dentists and pharmacists that are treating you that you are taking Apo-Diclo SR.

Things you must not do

Do not give Apo-Diclo SR to anyone else, even if they have the same condition as you.

Do not take any other medicines used to treat arthritis while you are taking Apo-Diclo SR without first telling your doctor. This includes:

- aspirin (also called ASA or acetylsalicylic acid)
- other salicylates
- other forms of Apo-Diclo SR
- any other NSAID medicine

If you take these medicines together with Apo-Diclo SR, they may cause unwanted effects.

If you need to take something for headache or fever, it is usually okay to take paracetamol. If you are not sure, ask your doctor.

Do not stop any other forms of treatment for arthritis that your doctor has told you to follow.

This medicine does not replace exercise or rest programs or the use of heat/cold treatments.

Do not use Apo-Diclo SR to treat any other medical complaints unless your doctor tells you to.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

As with other NSAID medicines, Apo-Diclo SR may cause dizziness, drowsiness or blurred vision in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking diclofenac or if you have any questions or concerns.

Like other medicines, diclofenac 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.

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

Do not be alarmed by the following list of side effects. You may not experience any of them.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

While taking it

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

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- loss of appetite
- constipation, diarrhoea, pain in the stomach, wind
- dizziness, light headedness
- drowsiness, sleepiness, disorientation
- buzzing or ringing in the ears
- change in mood, for example, feeling depressed, anxious or irritable
- trembling, sleeplessness, nightmares
- headache
- sore mouth or tongue
- hair loss or thinning
- altered taste sensation

See your doctor immediately if you notice any of the following:

- severe pain or tenderness in the stomach
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal; reddish or purplish blotches under the skin
- signs of anaemia such as tiredness, being short of breath, looking pale
- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- signs of a liver problem such as tiredness, lack of energy, itching of the skin, yellowing of the skin and eyes, pain in the abdomen
- unusual weight gain, swelling of ankles or legs
- symptoms of sunburn (such as redness, itching, swelling,

blistering) which may occur more quickly than normal

- eye problems such as blurred or double vision
- severe dizziness, spinning sensation
- severe or persistent headache
- tingling or numbness of the hands or feet
- fast or irregular heartbeat, also called palpitations
- difficulty hearing

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

- sudden and oppressive chest pain (signs of myocardial infarction or heart attack)
- breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash or hives
- fainting or seizures (fits)
- pain or tightness in the chest
- inability or difficulty to speak
- paralysis (signs of cerebral attack)
- stiff neck (signs of meningitis)
- raised blood pressure

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

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, 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 this medicine 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 it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Apo-Diclo SR come in two strengths:

- Apo-Diclo SR 75mg tablets are light pink, triangular, biconvex, bevelled-edge, film coated tablet. Engraved “APO” over “75” on one side, other side plain.
- Apo-Diclo SR 100mg

tablets are pink, round, biconvex, bevelled-edge, film coated tablet. Engraved “APO” over “100” on one side, other side plain.

Available in blister of 30, 60, 90, 100, 500 & 1000 tablets and bottles of 100, 500 and 1000 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Active Ingredient:

Each capsule contains either 75 mg or 100 mg of diclofenac sodium.

They also contain the following inactive ingredients:

Apo-Diclo SR 75mg:

- Microcrystalline Cellulose
- Hyetellose
- Dextrates
- Magnesium stearate
- Hypromellose
- Iron oxide red
- Macrogol 3350
- Titanium Dioxide
- Carnauba wax
- *Iron oxide yellow

*For Apo-Diclo SR 100mg only.

This medicine is lactose and gluten free.

Sponsor

Apotex NZ Ltd

32 Hillside Road

Wairau Valley, Auckland 0627

Telephone: (09) 444 2073

Fax: (09) 444 2951

E-mail:

NZcustomerservice@apotex.com

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