

Consumer Medicine Information

DICLAX SR

Diclofenac sodium SR 75 and 100mg tablets

What is in this leaflet

This leaflet answers some common questions about DICLAX SR tablets. 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 DICLAX SR against the benefits this medicine is expected to have for you.

If you have concerns about taking DICLAX SR 75mg and 100mg tablets, ask your doctor or pharmacist.

Keep this leaflet with your DICLAX SR tablets. You may need to read it again.

What are Diclax SR tablets used for

DICLAX SR tablets contain the active ingredient diclofenac.

Diclofenac belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines relieve the symptoms of pain and inflammation. They do not cure your condition

Diclax SR relieves pain and reduces inflammation (swelling and redness) that may occur in the following:

- different types of arthritis including rheumatoid arthritis and osteoarthritis
- other painful conditions where swelling is a problem such as back pain, rheumatism, muscle strains, sprains and tendonitis (eg. tennis elbow)
- menstrual cramps (period pain)

Your doctor may have prescribed DICLAX SR for another use. Ask your doctor if you have any questions about why DICLAX SR has been prescribed for you.

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

Before you use Diclax SR tablets

When you must not take it

Do not take this medicine if you have an allergy to:

- diclofenac sodium (the active ingredient in Diclax SR) or any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac
- aspirin
- any other NSAID medicine

Symptoms of an allergic reaction to these medicines may include:

- asthma or other breathing problems
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- skin rash, itching or hives
- fainting

These symptoms can be severe if you are allergic to Aspirin or NSAID and are taking DICLAX SR tablets.

Aspirin or NSAID are present in many medicines used to treat headache, period pain or other aches and pains. If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.

Do not take Diclax SR if at the present time you have an ulcer (gastric or duodenal) or bleeding from the stomach or bowel. Your stomach problem may become worse.

Diclax SR is not recommended for use in adolescent children.

Do not give Diclax SR 75mg and 100 mg SR tablets to children under 14 years of age.

There is not enough information on its use in this age group.

Do not take Diclax SR after the expiry date (EXP) printed on the pack.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not take Diclax SR if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Tell your doctor if, in the past, you have ever had:

- ulcers (gastric or duodenal)
- severe attacks of indigestion or other stomach trouble
- problems with your bowel (eg. Crohn's disease, ulcerative colitis)
- bleeding from your rectum (back passage)

Tell your doctor if you have or have ever had:

- diseases of the heart including high or low blood pressure
- problems with your kidneys or liver
- 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.

Diclax SR can hide some of the signs of infection such as pain, fever, swelling and/or redness. You may then think that you are better or that the infection is not serious.

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

Diclax SR is not recommended for use during pregnancy or breast-feeding. Ask your doctor for advice.

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.

Important examples are:

- aspirin, salicylates or other NSAID medicines
- warfarin or heparin - medicines used to stop blood clots
- medicines to treat heart conditions such as digoxin
- lithium, a medicine used to treat some types of depression
- diuretics, also called fluid or water tablets
- tablets used to treat diabetes
- methotrexate, a medicine used to treat arthritis and some cancers
- cyclosporin, a medicine used to suppress the immune system
- certain antibiotics called quinolones
- Corticosteroids (used to provide relief for inflamed areas of the body).
- high blood pressure medicines

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Diclax SR.

Using Diclax SR

How much to take

Your doctor will decide what dose and for how long you will need DICLAX SR tablets.

Your doctor and pharmacist will be able to tell you:

- how many tablets to take.
- how many times to take the tablets each day

- when to take the tablets

Diclax SR 75mg and 100mg are slow release tablets.

Adults

The usual daily dose of Diclax SR tablets is 75mg -150mg.

How to take it

DICLAX SR tablets must be swallowed whole with a glass of water. Do not chew the tablets.

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. The tablets should be taken with a meal.

How long to take it

Do not take Diclax SR for longer than your doctor says.

If you are taking Diclax 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 forget to take it

If you have forgotten to take one dose of DICLAX SR tablets and it is almost time to take your next scheduled dose, then skip the dose you have missed, and continue taking your DICLAX SR tablets as directed by your doctor or pharmacist.

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 the one that you missed.

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

Overdose

Immediately contact your doctor, Poisons Information Centre (phone 0800 POISON or 0800 764 766), or accident and emergency department at your nearest hospital, if you think that you or anyone else may have taken too much Diclax SR. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of DICLAX SR with you if you can.

Keep the telephone numbers for these places handy.

While you are using Diclax SR tablets

Things you must do

Tell all the doctors, dentists and pharmacists who are attending you that you are receiving DICLAX SR.

Tell your doctor if you become pregnant.

Take Diclax SR exactly as your doctor has prescribed.

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.

Tell your doctor if you feel that your condition is not improving or getting worse.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

If you are going to have surgery, make sure the surgeon and anaesthetist know that you are taking Diclax SR since NSAID medicines such as DICLAX SR can slow down blood clotting.

Tell your doctor if you get an infection while taking DICLAX SR tablets.

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Things you must not do

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

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

If you take these medicines together with Diclax 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 Diclax SR 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. It may harm them, even if their symptoms seem to be the same as yours.

Things to be careful of

Be careful when driving, operating machinery or performing jobs that need you to be alert until you are certain that Diclax SR does not affect your performance.

Side effects

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

Like other medicines, DICLAX SR can cause some side effects. If they occur, most of them are likely to be minor and temporary but some may be serious and will need medical attention.

Elderly people should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

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

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

- feeling sick - nausea
- vomiting
- heartburn,
- indigestion
- cramps
- loss of appetite
- constipation, diarrhoea, pain in the stomach, wind
- dizziness/ unsteadiness
- drowsiness
- confusion
- buzzing or ringing in the ears
- depression
- irritability/aggression
- tremor
- sleeplessness, nightmares
- headache
- sore mouth or tongue
- hair loss
- altered taste sensation

Tell 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 heart beat, also called palpitations
- difficulty hearing

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

If any of the following happen, stop taking Diclox SR and tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital:

- 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)

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

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

Storage conditions

Storage

Keep your medicine in the original container until it is time to take it. If you leave the tablets out of the original container, they will not keep well.

Keep your tablets in a cool dry place away from light where temperature stays below 25°C

Do not store Diclox SR or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a windowsill.

Heat and dampness can destroy some medicines.

As with all medicines, you should store your tablets out of reach of children.

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

Disposal

Tell your doctor if you stop taking the tablets or the tablets have passed their expiry date. Ask your pharmacist what to do with any tablets, which are left over.

Product description

What it looks like

Diclax SR 75mg SR Tablets: Pink triangular film coated tablets,

Diclax SR 100mg SR Tablets: Light red, circular, biconvex, film coated tablet.

Ingredients

Active ingredient

diclofenac sodium

Other ingredients (excipients):

Ethyl cellulose, magnesium stearate, polyvidone, stearic acid, hypromellose, diethyl phthalate, talc, titanium dioxide, iron oxide yellow (E 172), iron oxide red (E 172), macrogol 4000.

Sponsor

Diclax SR is supplied in New Zealand by:

Douglas Pharmaceuticals Limited
P O Box 45 027
Auckland 0651
New Zealand

This leaflet was prepared on 10 April 2007 based on the approved NZ data sheet for the above products.