

Aclin

contains the active ingredient sulindac

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Aclin.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Aclin against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What Aclin is used for

Aclin relieves pain and reduces inflammation (swelling, redness and soreness) that may occur in the following conditions:

- * various types of arthritis including osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and acute gouty arthritis
- * muscle and bone injuries such as sprains, strains, lower back pain and tendonitis (e.g. tennis elbow).

Aclin belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

Your doctor may have prescribed Aclin for another reason. Ask your doctor if you have any questions about why Aclin has been prescribed for you.

Aclin is available only with a doctor's prescription.

There is no evidence that Aclin is addictive.

Before you take Aclin

When you must not take it

Do not take Aclin if you are allergic to medicines containing sulindac, aspirin, any other NSAID or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

If you are allergic to aspirin or NSAIDs and take Aclin, the above symptoms may be severe.

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

Do not take Aclin if:

- * you are vomiting blood or material that looks like coffee grounds
- * you are bleeding from the back passage, have black sticky bowel motions (stools) or bloody diarrhoea.

Do not take Aclin if you are pregnant or intend to become pregnant.

Aclin may affect your developing baby if you take it during pregnancy.

Do not take Aclin if you are breastfeeding or plan to breastfeed.

The safety of Aclin in breastfeeding has not been established.

Do not take Aclin if the expiry date (Exp.) printed on the pack has passed.

Do not take Aclin if the packaging shows signs of tampering or the tablets do not look quite right.

Do not give Aclin to children.

Before you start to take it

Tell your doctor if you have allergies to:

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

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * heartburn, indigestion, stomach ulcer or other stomach problems
- * vomiting blood or bleeding from the back passage
- * kidney or liver problems

- * diabetes mellitus or sugar diabetes
- * high blood pressure or heart disease
- * a tendency to bleed or other blood problems
- * are undergoing a surgery
- * asthma.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you currently have an infection.

If you take Aclin while you have an infection, the tablets may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

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

Taking other medicines

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

Some medicines may be affected by Aclin, or may affect how well it works. These include:

- * aspirin, salicylates or other NSAIDs
- * warfarin, a medicine used to prevent blood clots
- * tablets used to treat diabetes
- * methotrexate, a medicine used to treat arthritis and some cancers
- * DMSO (dimethyl sulfoxide), another medicine used to treat arthritis
- * cyclosporin, a medicine used to suppress the immune system.

These medicines may be affected by Aclin, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Aclin

How much to take

The usual dose is 400 mg per day, taken as a single dose or twice a day.

Your doctor may advise you to take a different dose. This depends on your condition and whether or not you are taking any other medicines.

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

How to take Aclin

Swallow the tablets with a full glass of water.

When to take Aclin

Take Aclin during or immediately after food.

This will lessen the chance of a stomach upset.

If you take Aclin once a day, take the tablets in the evening.

If you forget to take Aclin

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 the missed dose 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 you missed.

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

If you have any questions about this, check with your doctor or pharmacist.

How long to take Aclin for

Keep taking Aclin for as long as your doctor recommends.

Depending on your condition, you may need Aclin for a few days, a few weeks or for longer periods.

As with other NSAIDs, if you are using Aclin for arthritis it will not cure your condition but it should help control pain, swelling and stiffness. If you have arthritis Aclin should be taken every day for as long as your doctor prescribes.

For sprains and strains, Aclin is usually only needed for a few days.

If you are not sure how long to take your tablets, talk to your doctor.

If you take too much Aclin (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Aclin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Aclin, you may feel dizzy, light-headed and have a decreased urine output. You may also become unconscious.

While you are taking Aclin

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Aclin.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Aclin.

If you become pregnant while taking Aclin, tell your doctor.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Aclin.

If you get an infection while taking Aclin, tell your doctor.

Aclin may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is less serious than it might be. Signs of an infection include fever, pain, swelling or redness.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not use Aclin to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how Aclin affects you.

Aclin may cause dizziness, lightheadedness or blurred vision in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous. If you drink alcohol, dizziness or light-headedness may be worse.

Things that would be helpful for your arthritis

Some self help measures suggested below may help your condition.

Talk to your doctor, physiotherapist, or pharmacist about these measures and for more information.

- * Weight - your doctor may suggest losing some weight to reduce the stress on your joints.

- * Exercise - may be recommended by your doctor or physiotherapist to help keep or improve movement and strengthen muscles. Ask a physiotherapist for an exercise plan suited to your condition. As a general rule if any exercise hurts then do not do it.
- * Rest - is important and is usually balanced with exercise and activity. Rest is needed when joints are hot, swollen or painful.
- * Heat - hot showers or baths may help to ease the pain and relax the muscles that can become tense with arthritis. Your physiotherapist or doctor can prescribe other forms of heat treatment.
- * Physical aids - are available to help with daily household tasks. For example, there are gadgets and aids to help turn on taps, remove screw tops, pick up objects and handles can be fitted in bathrooms. Ask your pharmacist or doctor to give you more information.

Side effects

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

Aclin helps most people with arthritis, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by this list of possible 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 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
- * headache
- * buzzing or ringing in the ears
- * nervousness
- * swelling of the hands, feet, ankles.

These are the more common side effects of Aclin. They are usually mild and often respond to a reduction in dosage.

Some of the stomach upsets, such as nausea and heartburn, may be reduced by taking the tablets with food.

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

- * severe pain or tenderness in the stomach
- * eye problems such as blurred vision
- * severe dizziness, spinning sensation
- * change in mood, for example, depression
- * tingling or numbness of the hands or feet
- * fast or irregular heartbeats, also called palpitations
- * difficulty hearing
- * signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- * bleeding or bruising more easily than normal
- * signs of anaemia, such as tiredness, being short of breath, and looking pale
- * yellowing of the skin and eyes, also called jaundice
- * a change in the colour of urine, blood in the urine
- * a change in the amount or frequency of urine passed,

burning feeling when passing urine

- * symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.

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

If any of the following happen, stop taking Aclin and tell your doctor immediately, or go to Accident and Emergency at the 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, hives
- * fainting, seizures or fits
- * pain or tightness in the chest.

These are serious side effects that need urgent medical attention or hospitalisation. These side effects are rare.

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

After taking Aclin

Storage

Keep Aclin 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.

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

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

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

Do not leave Aclin in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Aclin, or your tablets have passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

- * Aclin 100 - orange-yellow tablet marked "SD/100" on one side and a Greek alpha symbol on the reverse.
- * Aclin 200 - orange-yellow tablet marked "SD/200" on one side and a Greek alpha symbol on the reverse.

Each bottle contains 50 tablets.

Ingredients

The active ingredient in Aclin is sulindac. Each Aclin tablet contains 100 mg of sulindac. Each Aclin 200 contains 200 mg of sulindac.

The tablets also contain:

- * lactose
- * microcrystalline cellulose
- * povidone
- * sodium starch glycollate
- * quinoline yellow CI 47005
- * purified talc
- * magnesium stearate.

The tablets are gluten free.

Manufacturer

Aclin is made in Australia by:
Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
Phone: (02) 9298 3999

Australian registration numbers:

Aclin 100 - Aust R 17587
Aclin 200 - Aust R 10232

This leaflet was prepared on
23 August 2005.