

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## ACLIN

### *Sulindac Tablets 100mg and 200mg*



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## What is in this leaflet

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This leaflet answers some common questions about ACLIN.

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 ACLIN 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 the medicine.** You may need to read it again.

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## What ACLIN is used for

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ACLIN is used to treat:

- Osteoarthritis
- Rheumatoid arthritis
- Ankylosing spondylitis
- Joint problems such as acute painful shoulder
- Acute gouty arthritis
- Painful low back syndrome (low back pain, also referred to as lumbago).

ACLIN contains the active ingredient sulindac. It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

It works by relieving pain, inflammation and tenderness, and promotes joint mobility.

**Ask your doctor if you have any questions about why this medicine 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 known to be addictive.

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## Before you take ACLIN

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### *When you must not take it*

**You must not take ACLIN:**

- If you have an active peptic (stomach) ulcer or gastrointestinal (stomach or bowel) bleeding
- If you have a history of repeated gastrointestinal ulcer or bleeding
- If you are vomiting blood or material that looks like coffee grounds
- If you have bleeding from the rectum (back passage), have sticky black stools (bowel motions), or bloody diarrhoea
- If you have had an asthma attack, hives or itchy rash, or runny or blocked nose caused by aspirin or other NSAIDs
- If you recently had coronary artery bypass graft (CABG) surgery
- If you have severe heart failure.

**Do not take ACLIN if you have an allergy to:**

- Any medicine containing sulindac
- Any of the ingredients listed at the end of this leaflet
- Aspirin or any other NSAID medicines.

Some of the symptoms of an allergic reaction may include: 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.

**Do not give this medicine to a child under the age of 18 years.**

Safety and effectiveness in children younger than 18 years have not been established.

**Do not take this medicine after the expiry date printed on the pack 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 or have had any of the following medical conditions:**

- Heart problems such as cardiovascular (heart) disease, previous heart attack, CABG surgery, high blood pressure, angina or chest pain
- Stroke
- Diabetes
- Heartburn, indigestion, stomach ulcer or other stomach problems
- Asthma
- Kidney or liver problems
- Swelling of the feet or ankles (fluid retention or oedema)
- A tendency to bleed
- Any current infection

## Tell your doctor if:

- You are or have ever been dependent on alcohol
- You are or have been a smoker.

## Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

## Caution is advised in elderly people.

## If you have not told your doctor about any of the above, tell him/her before you start taking ACLIN.

## Taking other medicines

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

Some medicines and ACLIN may interfere with each other. These include:

- Aspirin, salicylates and other NSAIDs
- Medicines used to prevent blood clots such as warfarin
- Some medicines used to treat high blood pressure
- Some medicines used to treat diabetes
- Methotrexate, a medicine used to treat arthritis and some cancers
- DMSO (dimethyl sulfoxide), another medicine used to treat arthritis
- Ciclosporin, a medicine used to suppress the immune system.

These medicines may be affected by ACLIN or may affect how well ACLIN works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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## How to take ACLIN

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**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 bottle, ask your doctor or pharmacist for help.

Elderly patients may be more susceptible to the risk of adverse reactions (side effects) and therefore lower dosages are generally recommended.

ACLIN is not recommended for children.

### How much to take

The usual dose of ACLIN is 400mg daily, taken in divided doses. Your doctor may lower the dose depending on how you respond.

Ask your doctor or pharmacist if you have any questions.

### How to take it

Take the tablets during, or immediately after a meal with a glass of water. This will help reduce the chance of any unwanted stomach or bowel effects.

### When to take it

#### Take your medicine at about the same times each day.

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

It does not matter if you take this medicine before or after food.

### How long to take it

#### Continue taking your medicine for as long as your doctor tells you.

The duration for which you need to take this medicine will depend on what medical problem you are taking it for. Ask your doctor if you have any questions.

### If you forget to take it

**If you forget a dose, just take the next dose when it is due.**

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

This may increase the chance of you getting an unwanted side effect.

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

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

### If you take too much (overdose)

**Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that 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.

Symptoms of an overdose may include:

- Inability to think straight
- Coma
- Decreased urine production
- Low blood pressure

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## While you are taking ACLIN

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### Things you must do

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ACLIN.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time (like blood tests to check liver and kidney function) to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you get an infection while you are taking ACLIN.

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

**Things you must not do**

**Do not take ACLIN to treat any other complaints unless your doctor tells you to.**

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

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

**Things to be careful of**

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

This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol while you are taking this medicine, you may be at higher risk of side effects.

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## Side effects

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

This medicine 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 attention 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 the following lists of side effects. You may not experience any of them.**

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

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

- Stomach upset, including nausea (feeling sick), vomiting, indigestion
- Constipation, diarrhoea, stomach pain, wind
- Loss of appetite
- Dizziness, sleepiness, drowsiness
- Headache
- Feeling anxious
- Buzzing or ringing in the ears
- Swelling of the legs, ankles or feet.

The above list includes the more common side effects of your medicine.

They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- Severe pain or tenderness in the stomach
- Eye problems including blurred vision
- Severe dizziness or spinning sensation
- Changes in mood
- Fast and/or irregular heartbeat
- Unusual bruising or bleeding, reddish or purple blotches under the skin
- Signs of frequent infections such as fever, chills, sore throat or mouth ulcers

- Signs of anaemia such as tiredness, being short of breath and looking pale
- A change in the colour of urine, or blood in the urine
- An increase or decrease in the amount of urine passed, burning feeling when passing urine
- Yellowing of eyes or skin (jaundice)
- Symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- Skin hypersensitivity.

The above list includes less common but serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- Sudden or severe itching, skin rash, hives
- Fainting, seizures or fits
- Breathing problems including asthma, wheezing, shortness of breath
- Tightness in the chest or chest pain.

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

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

This list of side effects is not complete. Other side effects not listed above may also occur in some people.

Some of the side effects (for example blood pressure) can only be found when your doctor does tests from time to time to check your progress.

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## After using ACLIN

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### Storage

**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°C.**

Do not store ACLIN 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 medicines where children cannot reach them.**

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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## **Product description**

### ***What it looks like***

**ACLIN 100mg tablets** are 8 mm flat bevelled edge orange-yellow tablets marked with "SD" over breakline "100" on one side and "α" on the other side.

**ACLIN 200 mg tablets** are 10 mm flat bevelled edge orange-yellow tablets marked with "SD" over breakline "200" on one side and "α" on the other side.

### ***Ingredients***

Each ACLIN 100 mg and ACLIN 200 mg tablet contains sulindac 100 mg and 200 mg as the active ingredient, respectively.

Each ACLIN tablet also contains:

- Lactose
- Microcrystalline cellulose
- Povidone
- Sodium starch glycollate
- Quinoline yellow
- Talc
- Magnesium stearate.

This medicine does not contain sucrose, gluten or tartrazine.

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## **If you want to know more**

Should you have any questions regarding this product, please contact your pharmacist or doctor.

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd  
PO Box 11183  
Ellerslie  
Auckland.

Telephone: (09) 579 2792

### ***Date of Information***

15 December 2011  
(Based on datasheet dated 14 December 2011)