

# Consumer Medicine Information

## DACLIN

### *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 DACLIN. It does not contain all the information available on this medicine. 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 using DACLIN against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.  
Keep this leaflet. You may want to read it again.

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## What DACLIN is used for and how it works

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Your DACLIN tablets contain the active ingredient sulindac. Sulindac belongs to a group of medicines known as NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).

DACLIN is used to relieve symptoms of pain and inflammation in various different conditions including:

- rheumatoid arthritis
- osteoarthritis
- ankylosing spondylitis
- gouty arthritis
- muscle and bone injuries including back pain, sprains, strains or tennis elbow

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

DACLIN is available on prescription from your doctor.

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## Before you take DACLIN

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### *When you must not take it*

Do not take DACLIN if:

- **You are allergic to sulindac or any of the other ingredients listed at the end of this leaflet**  
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.
- **You are allergic to aspirin or any other NSAID medicine**
- **You have a history of peptic ulcers or have an active peptic ulcer**
- **You have, or have had inflammation of the lining of the stomach or bowel (e.g. Crohn's disease and ulcerative colitis)**
- **You are vomiting blood or material that looks like coffee grounds**
- **You are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea**

### *Before you take it*

Tell your doctor if:

- are allergic to any other substances, including foods, preservatives or dyes
- you have or have ever had:
  - heartburn, indigestion, stomach ulcer or other stomach problems
  - asthma
  - kidney or liver disease
  - high blood pressure or heart problems
  - diabetes mellitus
  - swelling of the ankles or feet (oedema – fluid retention)
  - a tendency to bleed
- you currently have an infection
- you are pregnant or planning on becoming pregnant
- you are breastfeeding or planning to breastfeed
- you are or have ever been dependant on alcohol
- you are or have been a smoker

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

Caution is advised in the elderly.

### ***Taking other medicines***

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

Medicines that may interfere with DACLIN include:

- Aspirin, salicylates or other NSAID medicines
- medicines used to prevent blood clots such as warfarin
- diuretics, also called fluid or water tablets
- medicines used to treat high blood pressure
- some medicines used to treat diabetes
- Methotrexate, a medicine used to treat arthritis and some cancers
- Cyclosporin, a medicine used to suppress the immune system

These medicines may be affected by DACLIN or may affect how well DACLIN works. You may need different amounts of your medicines or you may need to take a different medicine. It is therefore important that you discuss this with your doctor or pharmacist.

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

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## **How to take DACLIN properly**

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### ***How much to take***

**Your doctor will tell you how much DACLIN you need to take each day. It is important that you take DACLIN as directed by your doctor. Do not take more than the recommended dose.**

The usual dose of DACLIN is 400mg a day, taken in divided doses. Your doctor may however lower the dose depending on how you respond.

Elderly patients can be more susceptible to the risk of adverse reactions and therefore lower dosages are generally recommended.

DACLIN is not recommended for children.

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.

If you do not understand the directions on the bottle, ask your doctor or pharmacist for help.

### ***How long to take it***

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

If you are taking DACLIN for arthritis, it will help to control your condition but does not cure it. Therefore DACLIN must be taken everyday. Continue taking DACLIN for as long as your doctor prescribes.

For muscle sprains and strains, you may only need to take DACLIN for a few days.

If you are not sure how long to continue taking DACLIN, ask your doctor.

### ***If you forget a dose***

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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## **While you are taking DACLIN**

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

Before you start any new medicine, tell your doctor or pharmacist that you are taking DACLIN.

Tell your doctor if you develop a skin rash or hives, problems with your vision, or if you become pregnant while taking DACLIN.

If you plan to have surgery, tell the surgeon or anaesthetist that you are taking DACLIN.

If you are going to have any blood tests, tell your doctor that you are taking DACLIN.

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

Do not take DACLIN to treat any other complaints, unless your doctor specifically tells you to.

Do not stop taking DACLIN or change the dose, without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

**DACLIN may cause dizziness or tiredness in some people.** Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that DACLIN does not affect your performance.

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## **Side effects**

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

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

**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

These are the more common side effects of DACLIN.

**Tell your doctor immediately if you experience:**

- severe pain or tenderness in the stomach
- eye problems including blurred vision
- severe dizziness or spinning sensation
- sudden 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

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

**If any of the following happen, stop taking DACLIN and tell your doctor immediately:**

- 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

These are very serious side effects. If you have them, you may have had a serious allergic reaction to DACLIN. You may need serious medical attention or hospitalisation. All of these side effects are very rare.

**The list of side effects mentioned above is not complete.** If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

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

If you are taking DACLIN long term your doctor may wish to check that your liver and kidney function is not being affected. The doctor will determine if this is necessary in a case-by-case manner.

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## **In case of overdose**

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You should only take the number of tablets that you have been told.

**Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any DACLIN by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.** Take the container of DACLIN with you if you can.

Keep telephone numbers for these places handy.

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## **Storage conditions**

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Do not take this medicine after the expiry date shown on the label or if the packaging shows signs of tampering.

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

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

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

## ***Disposal***

If your doctor tells you to stop taking DACLIN or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

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## **Product Description**

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### ***What DACLIN tablets look like***

DACLIN tablets 100mg are yellow round tablets with a bisect on one side.

DACLIN tablets 200mg are yellow round tablets with a bisect on one side.

Each DACLIN tablet contains the active ingredient sulindac.

Each DACLIN tablet also contains lactose, microcrystalline cellulose, povidone, sodium starch glycollate, quinoline yellow lake, magnesium stearate, talc.

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

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

### ***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***

2 February 2009  
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