

# Actigall®

300mg capsules

*Ursodiol (Ursodeoxycholic acid)*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about Actigall.

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 this medicine against the benefits it can provide.

**If you have any concerns about 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 Actigall is used for

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Actigall is used in the treatment of gallstone disease. It is taken by mouth to dissolve the gallstones.

Actigall is used in patients with gallstones who do not need to have their gallbladders removed or in those in who surgery should be avoided because of other medical problems. However Actigall works only in those patients whose gallstones are made of cholesterol and works best when these stones are small and of the “floating” type.

The symptoms of these disorders vary from person to person. Your doctor can provide you with more information.

**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 purpose.

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

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### Before you take Actigall

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#### ***When you must not take it***

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

- ursodeoxycholic acid (the active ingredient) or any of the other ingredients of Actigall listed at the end of this leaflet
- or other products containing bile acids.

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.

**Tell your doctor if you are taking any other medications before starting Actigall treatment.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist.

#### ***Before you start to take it***

**Tell your doctor if you have any of the following health problems/medical conditions:**

- severe liver or kidney disease

Your doctor may not want you to take this medicine or may want to take special precautions if you have any of the above conditions.

It is important that your doctor checks that your liver is working

properly at the start of treatment. A laboratory test needs to be done.

**It is thought that body weight and the kind of diet the patient follows may affect how fast the stones dissolve and whether new stones will form. However check with your doctor before going on any diet.**

**Tell your doctor if you are pregnant or intend to become pregnant.**

This medicine may affect your baby if you take it while you are pregnant, and is not recommended for use during pregnancy.

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

Caution should be exercised when Actigall is administered while breast feeding, as it is not known if Actigall passes into the breast milk.

**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.

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

**Tell your doctor or pharmacist 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 and Actigall may interfere with each other. These include:

- Bile sequestering agents (cholestyramine, colestipol)
- Aluminium based antacids
- Oestrogens, oral contraceptives and clofibrates

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

**If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.**

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## How to take Actigall

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

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### **How much to take**

The dose of Actigall will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of Actigall. If your dose is different, do not change it unless your doctor tells you to do so.

- For gallstone disease:

The dose is based on body weight and must be determined by your doctor. The usual dose is 10-12mg/kg of body weight once a day. Each dose is usually taken with a meal.

In patients taking bile acid binding resins, Actigall should be administered either 2-3hours before or 4 hours after the doses of resins.

### **When to take it**

**Take the capsules as advised by your doctor or pharmacist.**

### **How to take it**

**Swallow the capsules with a full glass of water. If your stomach is upset after taking the capsules, take them with a meal or after a snack.**

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

**Take this medicine until your doctor tells you to stop treatment.**

The length of treatment will depend on your condition and on how well the medicine works.

### **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 one when you are meant to.**

**Otherwise, take the dose as soon as you remember, and then go back to taking the tablets as you would normally.**

**You can 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.**

### **If you take too much (Overdose)**

**Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to Accident and Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much Actigall. Do this even if there are no signs of discomfort or poisoning.**

**Keep the telephone numbers for these places handy.**

If you take too much Actigall, you may develop diarrhoea which should be treated symptomatically.

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## While you are taking Actigall

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### **Things you must do**

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

Your doctor can discuss with you the risks of taking it while you are pregnant.

**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 and check your heart and blood pressure from time to time. This helps to prevent unwanted side effects.

**It is important that your doctor checks your progress at regular visits.**

Laboratory tests will have to be done every few months while you are taking this medicine to make sure that the gallstones are dissolving and your liver is working properly.

**Before having any surgery or emergency treatment, even a minor procedure, tell the doctor or dentist in charge that you are taking Actigall or have been taking it within the last two weeks or so.**

If possible, this medicine should be stopped before surgery to avoid unnecessary side effects.

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

**Tell any other doctor, dentist or pharmacist who treats you that you are taking Actigall.**

### **Things you must not do**

**Do not stop taking Actigall or change the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.** If you stop taking this medicine suddenly, your condition may worsen or you may have unwanted side effects.

**Do not give this medicine to anyone else, even if their condition seems similar to yours.**

**Do not use it to treat any other complaints unless your doctor tells you to.**

### **Things to be careful of**

**Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Actigall until you know how it affects you.**

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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 Actigall.**

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 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.

**Do not be alarmed by these lists 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 these side effects and they worry you:**

- diarrhoea
- back pain
- nausea (feeling sick), vomiting
- hair loss
- heartburn
- itching

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing
- Severe diarrhoea

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

Some people may have other side effects not yet known or mentioned in this leaflet.

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## After using Actigall

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### Storage

- Keep your medicine in the original container until it is time to take a dose.
- Store it in a cool dry place at room temperature.
- Do not store Actigall or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

**Keep the capsules 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 you have left over.**

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## Product description

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### What it looks like

Actigall is supplied in 300mg hard gelatine capsules with a pink cap and white body, containing a white/yellowish powder, branded in black with "Actigall" on one part and "300mg" on the other. Each pack of Actigall contains 100 capsules.

### Ingredients

Actigall capsules contain 300 mg of ursodiol as the active ingredient.

They also contain:

- Starch
- Colloidal silicon dioxide
- Magnesium stearate
- Gelatine
- Black ink

### Sponsor

Actigall is supplied in New Zealand by:

NOVARTIS New Zealand Limited  
Novartis New Zealand Limited  
Private Bag 65904  
Mairangi Bay  
Auckland

Building G, 5 Orbit Drive  
Rosedale  
Auckland 0632  
Telephone: 0800 652 422

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