

Progout

contains the active ingredient allopurinol

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Progout.

It does not contain all 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 Progout against the benefits expected 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 Progout is used for

Progout is used in the treatment of:

- * gouty arthritis or gout, a condition of painful swollen joints caused by uric acid crystals
- * kidney stones
- * other rare conditions where high levels of uric acid occur in the blood, for example Lesch-Nyhan syndrome.

Progout helps to treat the symptoms of these conditions but will not cure them. It will not help treat the pain that occurs in an acute attack of gout.

Progout belongs to a group of medicines called anti-uricaemic agents. These medicines work by reducing the formation and accumulation of uric acid in the

body. Excess amounts of uric acid in the blood may lead to the development of crystals which deposit in the joints, causing pain, swelling and tenderness.

Ask your doctor if you have any questions about why Progout has been prescribed for you.

Your doctor may have prescribed Progout for another reason.

Progout is available only with a doctor's prescription.

There is no evidence that Progout is addictive.

Before you take Progout

When you must not take it

Do not take Progout if you are allergic to medicines containing allopurinol (e.g. Zyloprim) 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.

Do not take Progout if:

- * you or a member of your immediate family have haemochromatosis, a condition where there is too much iron in the body, and you are also taking iron salts at the same time

- * you are having an acute attack of gout.

Do not take Progout if the expiry date (EXP.) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Progout if the packaging shows signs of tampering or the tablets do not look like the tablets described at the end of this leaflet.

Before you start to take it

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

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking Progout during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Progout passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Progout when breastfeeding.

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

- * liver problems
- * kidney problems
- * high blood pressure
- * heart failure or other heart problems
- * diabetes mellitus
- * cancer or tumours.

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

Tell your doctor if you plan to have surgery.

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

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 Progout, or may affect how well it works. These include:

- * aspirin and other salicylates
- * probenecid, a medicine used to treat gout
- * warfarin (Coumadin, Marevan), a medicine used to prevent blood clots
- * azathioprine (e.g. Imuran) and cyclosporin (Neoral, Sandimmun), medicines used to prevent organ transplant rejection or to treat certain the immune system problems
- * mercaptopurine (Puri-Nethol), a medicine used in the treatment of leukaemia
- * chlorpropamide, a medicine for diabetes
- * phenytoin (Dilantin), a medicine for epilepsy
- * theophylline (Nuelin), a medicine used in asthma
- * antibiotics called amoxicillin (e.g. Amoxil, Moxacin) and ampicillin (Alphacin)
- * thiazide diuretics or fluid tablets (e.g. Dithiazide).

Your doctor can tell you what to do if you are taking any of these medicines.

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 Progout.

How to take Progout

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 bottle, ask your doctor or pharmacist.

How much to take

The dose varies from person to person. Your doctor will tell you how much to take.

The usual dose is 100 mg to 200 mg once daily for mild conditions, 300 mg to 600 mg daily for moderately severe conditions and 700 mg to 900 mg daily for severe conditions.

Elderly people over 65 years of age and those with kidney or liver problems may need smaller doses.

Children under 15 years of age usually take 100 mg to 400 mg daily.

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.

How to take Progout

Swallow the tablets with a glass of water.

It is important to drink at least 2 litres of fluid each day when you have high levels of uric acid in the blood.

When to take Progout

Take Progout during or immediately after food.

This will lessen the chance of a stomach upset.

Progout is usually taken once a day. However, if your dose is higher than 300 mg a day, your doctor may advise you to take it morning and night.

If you forget to take Progout

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 Progout for

To properly control your condition, Progout must be taken every day.

Progout will not cure your condition but will help control pain, stiffness and other symptoms.

Keep taking Progout for as long as your doctor recommends.

If you take too much Progout (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 Progout. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Progout, you may feel dizzy, nauseous, and experience vomiting and diarrhoea.

While you are taking Progout

Things you must do

Drink at least 2 litres (8 to 10 glasses) of fluid each day.

This will help to reduce the levels of uric acid in your body and prevent the formation of kidney stones.

Stop taking Progout immediately if you develop a skin rash or any other sign of an allergic reaction.

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

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

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

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

You may need to have blood or urine tests.

Tell your doctor if you feel Progout is not helping your condition.

If you continue to have painful attacks of gout your doctor may need to adjust your treatment.

Tell your doctor if, for any reason, you have not taken Progout exactly as prescribed.

Otherwise, your doctor may adjust your treatment unnecessarily.

Things you must not do

Do not take Progout to treat an acute attack of gout.

Your doctor will prescribe another medicine such as colchicine or a non-steroidal anti-inflammatory drug (NSAID) to relieve an acute attack of gout.

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

Do not give Progout 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 Progout affects you.

Progout may cause drowsiness, dizziness or lack of co-ordination in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Avoid drinking alcohol while taking Progout.

Combining Progout and alcohol can make you more sleepy, dizzy or lightheaded. Alcohol may also increase the formation of uric acid.

Certain foods are best avoided when you have gout.

Food such as organ meats, anchovies and yeast extracts (includes Vegemite(R)) can increase the levels of uric acid in your body. Ask your doctor or pharmacist for more advice about which foods to avoid.

Side effects

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

Progout helps most people with gouty arthritis and kidney stones, but it may have unwanted side effects in some people.

Side effects only occur rarely in people taking Progout. Most of the time they are minor. You may need medical treatment if you get some of the side effects.

People with liver and kidney problems have an increased chance of experiencing 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:

- * nausea, vomiting
- * headache
- * drowsiness, dizziness, unsteadiness when walking
- * change in taste sensation
- * change in bowel habits
- * hair loss or discolouration.

These reactions are usually mild.

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

- * signs of liver problems such as yellowing of the skin and eyes, dark coloured urine and generally feeling unwell
- * tingling or numbness of the hands or feet
- * visual disturbances
- * excessive thirst, going to the toilet more often, a burning feeling when passing urine
- * blood in the urine
- * frequent infections such as fever, severe chills, sore throat or mouth ulcers
- * bleeding or bruising more easily than normal
- * swelling of the hands, feet or ankles
- * general feeling of being unwell or depression.

These side effects can be serious and you may need medical attention.

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

- * severe itching, skin flaking, skin rash or hives
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

- * wheezing or shortness of breath
- * pain or tightness in the chest
- * seizures (fits).

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

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

Other side effects not listed above may also occur in some patients. Some of these side effects (e.g. high blood pressure) can only be found when your doctor does tests from time to time to check your progress.

After taking Progout

Storage

Keep Progout 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 25 degrees C.

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

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

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Progout tablets are available 2 strengths:

- * Progout 100 - round, white, scored tablet marked "AL/100" on one side and "G" on the other
- * Progout 300 - round, white, scored tablet marked "AL/300" on one side and "G" on the other.

Progout 100 is available in bottles of 100 tablets and Progout 300 in bottles of 60 tablets.

Ingredients

The active ingredient in Progout is allopurinol.

Progout 100

Each Progout 100 tablet contains 100 mg of allopurinol.

The tablets also contain:

- * lactose
- * maize starch
- * povidone
- * macrogol 8000
- * sodium lauryl sulfate
- * purified talc
- * magnesium stearate.

Progout 100 tablets are gluten free

Progout 300

Each tablet Progout 300 contains 300 mg of allopurinol.

The tablets also contain:

- * maize starch
- * povidone
- * maltodextrin
- * sodium starch glycollate
- * microcrystalline cellulose
- * magnesium stearate.

Manufacturer

Progout 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

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Progout 100 - AUST R 27969

Progout 300 - AUST R 17708

This leaflet was prepared on 5 August 2005.