

PROGOUT® VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking PROGOUT VIATRIS?

PROGOUT VIATRIS contains the active ingredient allopurinol. PROGOUT VIATRIS is used to treat: gouty arthritis or gout kidney stones rare conditions where high levels of uric acid occur in the blood (for example, Lesch-Nyhan syndrome). For more information, see Section [1. Why am I taking PROGOUT VIATRIS?](#) in the full CMI.

2. What should I know before I take PROGOUT VIATRIS?

Do not take if you have ever had an allergic reaction to PROGOUT VIATRIS or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more

information, see Section [2. What should I know before I take PROGOUT VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PROGOUT VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take PROGOUT VIATRIS?

Swallow the tablets whole with a full glass of water.

More instructions can be found in Section [4. How do I take PROGOUT VIATRIS?](#) in the full CMI.

5. What should I know while taking PROGOUT VIATRIS?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are taking PROGOUT VIATRIS● Drink at least two litres (8-10 glasses) of fluid each day● Tell your doctor if you have an acute attack of gout while you are
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	<p>taking PROGOUT VIATRIS</p> <ul style="list-style-type: none"> ● Tell your doctor immediately if you become pregnant or plan to breastfeed while taking PROGOUT VIATRIS.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not take this medicine to treat any other complaints unless your doctor tells you to ● Do not stop taking this medicine or lower the dosage without checking with your doctor ● Do not give this medicine to anyone else, even if they have the same condition as you ● Do not take PROGOUT VIATRIS to treat an acute attack of gout.
<p>Driving or u machines</p>	<ul style="list-style-type: none"> ● PROGOUT VIATRIS may cause dizziness, drowsiness, lack of co-ordination in some people. Make sure you know how you are affected by this medicine

	before you drive or use machinery.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Keep PROGOUT VIATRIS in a cool dry place where the temperature will stay below 25°C.

For more information, see Section [5. What should I know while taking PROGOUT VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Stomach upsets, including nausea, vomiting, dizziness, drowsiness, headache, change in taste sensation, sleeplessness, hair loss. **Serious side effects:** changes in vision, tingling or numbness of the hands or feet, a change in the amount of urine passed, yellowing of the skin and eyes (jaundice), generally feeling of being unwell or depressed, frequent infections such as fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily, angina or palpitations, swelling of the hands, ankles or legs. **Very serious side effects:** asthma, wheezing or shortness of breath, swelling of the face, lips, tongue or throat which may cause difficulty in breathing, sudden or severe itching, skin rash or hives, other skin problems, fainting, seizures or fits, pain or tightness in the chest. For more information, including

what to do if you have any side effects, see Section [6](#).
[Are there any side effects?](#) in the full CMI.

PROGOUT® VIATRIS

Active ingredient(s): *allopurinol*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking PROGOUT VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking PROGOUT VIATRIS.**

Where to find information in this leaflet:

- [1. Why am I taking PROGOUT VIATRIS?](#)
- [2. What should I know before I take PROGOUT VIATRIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take PROGOUT VIATRIS?](#)
- [5. What should I know while taking PROGOUT VIATRIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking PROGOUT VIATRIS?

PROGOUT VIATRIS contains the active ingredient allopurinol.

PROGOUT VIATRIS is used to treat:

- gouty arthritis or gout
- kidney stones

- rare conditions where high levels of uric acid occur in the blood (for example, Lesch-Nyhan syndrome).

It belongs to a group of medicines called anti-uricaemic agents.

PROGOUT VIATRIS works by reducing the production of uric acid in the body, therefore helping to prevent the formation of deposits of uric acid crystals. Deposits of uric acid crystals in the body can cause a variety of medical problems.

High levels of uric acid may cause gout attacks or kidney stones. PROGOUT VIATRIS is used to prevent gout attacks, not to treat them once they occur.

Ask your doctor if you have any questions about why this PROGOUT VIATRIS has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I take PROGOUT VIATRIS?

Warnings

Do not take PROGOUT VIATRIS if:

- you are allergic to any medicine containing allopurinol, or any of the ingredients listed at the end of this leaflet.

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
- muscle pain or tenderness or joint pain

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Emergency department at the nearest hospital.

Always check the ingredients to make sure you can take this medicine.

- you or a member of your immediate family has been diagnosed with haemochromatosis (a disease involving too much iron in the body) and you are taking iron salts.
- the expiry date printed on the pack has passed 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 PROGOUT VIATRIS, talk to your doctor.

Check with your doctor if you:

- have or have had any other medical conditions including:
 - kidney problems, including kidney stones
 - liver problems

- high blood pressure
- heart problems
- conditions where the levels of uric acid are abnormally high
- cancer or tumours
- thyroid problems
- diabetes
- epilepsy
- have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are currently having an attack of gout.

Treatment with PROGOUT VIATRIS should not be started until the attack has stopped, otherwise more attacks may occur.

(However, if an attack of gout occurs when a person is already taking allopurinol, it can be continued).

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

PROGOUT VIATRIS passes into breast milk and may affect your baby. Your doctor can discuss with you the risks and benefits involved.

Use in children

There is not enough information to recommend the use of this medicine for children.

3. What if I am taking other medicines?

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

- **Some medicines may interfere with PROGOUT VIATRIS and affect how it works. These include:**
- some medicines used to treat high blood pressure or heart problems
- thiazide diuretics (a certain type of water tablet)
- mercaptopurine, azathioprine or ciclosporin - medicines used to suppress the immune system
- aspirin and other medicines known as salicylates
- probenecid, a medicine used to treat gout or hyperuricaemia (high levels of uric acid in the blood)
- warfarin and other coumarin type anticoagulant medicines, used to help prevent blood clots
- chlorpropamide, a medicine used to treat diabetes

- phenytoin, a medicine used to treat epilepsy
- certain antibiotics such as ampicillin and amoxicillin
- theophylline, a medicine used to treat asthma
- aluminium hydroxide, a medicine used to treat the symptoms of too much stomach acid
- adenine arabinoside ('Vidarabine'), an anti-viral medicine
- medicines used for cancer (e.g. cyclophosphamide, doxorubicin)
- didanosine, used to treat HIV infection.

Other medicines not listed above may also interact with PROGOUT VIATRIS.

You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PROGOUT VIATRIS.

4. How do I take PROGOUT VIATRIS?

How much to take

- Your doctor will tell you how much PROGOUT VIATRIS you should take. This will depend on your condition and whether you are taking any other medicines.
- Follow the instructions provided and take PROGOUT VIATRIS until your doctor tells you to stop.
- The usual adult dose range is:

- 100 - 200 mg per day for mild conditions
- 300 - 600 mg per day for moderately severe conditions
- 700 - 900 mg per day for severe conditions.
- People over 65 years of age, and those with kidney and/or liver problems should be started on the lowest dose possible to control uric acid production.
- Children under 15 years of age usually take 100 - 400 mg per day.

How to take PROGOUT VIATRIS

- Swallow the tablets whole with a full glass of water.

When to take PROGOUT VIATRIS

- PROGOUT VIATRIS should be taken immediately after food, as this will lessen the chance of a stomach upset.
- Take PROGOUT VIATRIS at the same time each day. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.
- PROGOUT VIATRIS is usually taken once daily. However, if your dose is more than 300 mg, your doctor may advise you to take your medicine twice a day. Then, it should be taken morning and night, after breakfast and dinner.

How to long to take PROGOUT VIATRIS

- **Continue taking PROGOUT VIATRIS for as long as your doctor tells you.**

PROGOUT VIATRIS helps to control your condition, but does not cure it. It is important to keep taking PROGOUT VIATRIS even if you feel well.

Make sure you have enough to last over weekends and holidays.

If you forget to take PROGOUT VIATRIS

If it is less than 4 hours to your next dose, skip the dose you missed and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose 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 PROGOUT VIATRIS

If you think that you or anyone else has taken too much PROGOUT VIATRIS, urgent medical attention maybe needed.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- diarrhoea
- dizziness.

5. What should I know while taking PROGOUT VIATRIS?

Things you should do

- **You should drink at least two litres (8 - 10 glasses) of fluid each day.**

This will assist in reducing the uric acid levels in your body and prevent kidney stones from forming.

- **Tell your doctor if you have an acute attack of gout while you are taking PROGOUT VIATRIS.**

Your doctor may prescribe a medicine to relieve the acute attack. You can continue taking PROGOUT VIATRIS.

- **If you are about to start any new medicine, remind your doctor and pharmacist that you are taking PROGOUT VIATRIS.**
- Remind any doctor, dentist or pharmacist you visit that you are taking PROGOUT VIATRIS.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking PROGOUT VIATRIS.
- **If you become pregnant or plan to breastfeed while taking PROGOUT VIATRIS, tell your doctor immediately.**
- If you are about to have any blood tests, tell your doctor that you are taking PROGOUT VIATRIS.
- Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- Do not take PROGOUT VIATRIS to treat any other complaints unless your doctor tells you to.

- Do not give PROGOUT VIATRIS to anyone else, even if they have the same condition as you.
- Do not stop taking PROGOUT VIATRIS or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen. If possible, your doctor will gradually reduce the amount you take each day before stopping PROGOUT VIATRIS completely.

- Do not take PROGOUT VIATRIS to treat an acute attack of gout.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PROGOUT VIATRIS affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it.

If you take the tablets out of their original packaging it may not keep well.

- Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy the medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● stomach upsets, including nausea, vomiting or diarrhoea● dizziness, drowsiness or unsteadiness when walking● change in bowel habits● headache● change in taste sensation● sleeplessness● hair loss or change in hair colour.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● changes in vision● tingling or numbness of the hands or feet● a change in the amount of urine passed, going to the toilet more often or a burning feeling while passing urine● blood in your urine● yellowing of the skin and eyes (jaundice)● generally feeling of being unwell or depressed● frequent infections such as fever, severe chills, sore throat or mouth ulcers● bleeding or bruising more easily● angina or palpitations● swelling of the hands, ankles or legs.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">• asthma, wheezing or shortness of breath• swelling of the face, lips, tongue or throat which may cause difficulty in breathing• sudden or severe itching, skin rash or hives, other skin problems• fainting, seizures or fits• pain or tightness in the chest.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>These side effects are rare.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What PROGOUT VIATRIS contains

Active ingredient (main ingredient)	allopurinol (100 mg and 300 mg)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● lactose monohydrate● maize starch● povidone● sodium starch glycollate type A● sunset yellow FCF (300 mg only)

	<ul style="list-style-type: none"> • stearic acid
Potential allergens	<ul style="list-style-type: none"> • sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What PROGOUT VIATRIS looks like

- **PROGOUT VIATRIS 100 mg tablets:** White to off-white coloured, round biconvex, uncoated tablets with 'AL' & '100' separated by breakline on one side and plain on the other side (AUST R 269653).

Available in bottles of 200 tablets.

- **PROGOUT VIATRIS 300 mg tablets:** Peach coloured, round, biconvex uncoated tablets with 'AL' & '300' separated by breakline on one side and plain on the other side (AUST R 269642).

Available in blister packs of 60 tablets.

Who distributes PROGOUT VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in May 2025.

PROGOUT® is a Viatris company trade mark

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