**Package leaflet: Information for the patient**

**Allopurinol Sandoz® tablet 100 mg, tabletten**
**Allopurinol Sandoz® tablet 300 mg, tabletten**

allopurinol

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What [Nationally completed name] is and what it is used for

- [Nationally completed name] belongs to a group of medicines called enzyme inhibitors, which act to control the speed at which special chemical changes occur in the body.
- [Nationally completed name] is used for the long term, preventative treatment of gout and may be used in other conditions associated with an excess of uric acid in the body, including kidney stones and other types of kidney disease.

## 2. What you need to know before you take [Nationally completed name]

**Do not take [Nationally completed name]**
- if you are allergic to allopurinol or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**
Talk to your doctor or pharmacist before taking [Nationally completed name] if:
- you are of Han Chinese, African or Indian origin

- you have problems with your liver and kidneys. Your doctor may give you a lower dose or ask you to take it less often than each day. They will also monitor you more closely.
  - You have heart problems or high blood pressure and you take diuretics and/or medicines called ACE-inhibitors.
- You are currently having an attack of gout.
- you have thyroid problems.

If you are not sure if any of the following applies to you, talk to your doctor or pharmacist before taking allopurinol.

Serious skin rashes (Hypersensitivity syndrome, Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported with the use of allopurinol. Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin.
These serious skin rashes can be more common in people of Han Chinese, Thai or Korean origin. Chronic kidney disease may increase the risk in these patients additionally.
If you develop a rash or these skin symptoms, stop taking allopurinol and contact your doctor immediately.

If you have cancer or Lesch-Nyhan syndrome the amount of uric acid may increase in your urine. To prevent this, you need to assure to drink sufficiently to dilute your urine.

In case you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.

**Children**
Use in children is rarely indicated, except in some types of cancer (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

**Other medicines and [Nationally completed name]**
**Tell your doctor before you start to take this medicine if you are taking:**
- 6-mercaptopurine ( used to treat blood cancer)
- azathioprine, cyclosporine (used to suppress the immune system)
  Please note, cyclosporine side effects may occur more frequently.
- vidarabine (used in the treatment of herpes)
  Please note, vidarabine side effects can occur more frequently. Take special care if these occur.
- didanosine, a medicine to treat HIV infection
- salicylates (used to reduce pain, fever or inflammation e.g. acetylsalicylic acid)
- probenecid (used to treat gout)
- chlorpropamide (used to treat diabetes)
  Chlorpropamide dose reduction may be necessary, particularly in patients with reduced kidney function.
- warfarin, phenprocoumon, acenocoumarol (used to thin the blood)

Your doctor will monitor your blood clotting values more frequently and if necessary, reduce the dose of these medicines.
- phenytoin (used to treat epilepsy )
- theophylline (used to treat asthma and other breathing diseases)
  Your doctor will measure theophylline blood levels, particularly when treatment with allopurinol begins, or following any dose changes.
- ampicillin or amoxicillin (used to treat bacterial infections)
  Patients should receive other antibiotics where possible, as allergic reactions are more likely to occur.
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics)
- medicines to treat aggressive tumours, such as
  - cyclophosphamide
  - doxorubicin
  - bleomycin
  - procarbazine
  - alkyl halides

  Your doctor will monitor your blood counts frequently.
- didanosine (used to treat HIV infection)
- captopril (used to treat high blood pressure)
- If aluminium hydroxide is taken concomitantly, allopurinol may have an attenuated effect. There should be an interval of at least 3 hours between taking both medicines.
- With administration of allopurinol and cytostatics (e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides), blood dyscrasias occur more frequently than when these active substances are administered alone. Blood count monitoring should therefore be performed at regular intervals.

The risk of skin reactions can be raised, especially if your kidney function is chronically reduced.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Pregnancy and breast-feeding**
Allopurinol is excreted in the human breast milk. Allopurinol during breast-feeding is not recommended.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**
Allopurinol Tablets can cause dizziness, drowsiness, and can affect your coordination. If you are affected, DO NOT drive, operate machinery or participate in dangerous activities.

**[Nationally completed name] contains lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take [Nationally completed name]

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will usually start with a low dose of allopurinol (e.g. 100 mg/day), to reduce the risk of possible side effects. Your dose will be increased if necessary.

The tablets should be swallowed preferably with a drink of water. The score line is only there to help you break the tablet if you have difficulty swallowing it whole. You should take your tablets after a meal. You should drink plenty of fluids (2-3 liters a day) while you are taking this medicine.

The recommended dose is:

**Use in adults (including the elderly)**
Starting dose: 100 - 300 mg/day.
When you start your treatment, your doctor may also prescribe an anti-inflammatory medicine or colchicine for a month or more, to prevent attacks of gouty arthritis.
Your dose of allopurinol may be adjusted depending on the severity of the condition. The maintenance dose is:
- mild conditions, 100-200 mg/day
- moderately severe conditions, 300-600 mg/day
- severe conditions, 700-900 mg/day.

Your dose may also be altered by your doctor if you have reduced kidney and liver function, particularly if you are elderly.
If the daily dose exceeds 300 mg/day and you are suffering from gastro-intestinal side effects such as nausea or vomiting (see section 4), your doctor may prescribe allopurinol in divided doses to reduce these effects.

**If you have a serious kidney problem**
- you may be asked to take less than 100 mg each day
- or you may be asked to take 100 mg at longer intervals than one day.

If you have dialysis two or three times a week, your doctor may prescribe a dose of 300 or 400 mg which is to be taken straight after your dialysis.

**Use in children and adolescents**
[Nationally completed name 100 mg tablets]
**Use in children (under 15 years)** weighing 15 kg or more
[Nationally completed name 300 mg tablets]
**Use in children (under 15 years)** weighing 45 kg or more
Usual dose: 10 to 20 mg per kilogram bodyweight daily, divided into 3 doses.
Maximum dose: 400 mg allopurinol daily.
Treatment may be started together with an anti-inflammatory medicine or colchicine, and the dose adjusted if you have reduced kidney and liver function, or divided to reduce gastro-intestinal side effects, as for Adults above.

**If you take more [Nationally completed name] than you should**

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.
An overdose is likely to cause effects including nausea, vomiting, diarrhoea, or dizziness.
Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

**If you forget to take [Nationally completed name]**
If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one.
DO NOT take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

**If you stop taking [Nationally completed name]**
You should continue to take these tablets for as long as your doctor tells you to. DO NOT stop taking your medicine without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**If you experience any of the following, stop your tablets and tell your doctor immediately:**

**Hypersensitivity**
Symptoms may include:
**Uncommon** (may affect up to 1 in 100 people)
If you have an allergic reaction, stop taking [Nationally completed name] and see a doctor straight away. The signs may include:
- flaking skin, boils or sore lips and mouth
- very rarely signs may include sudden wheeziness, fluttering or tightness in the chest and collapse.

Do not take any more tablets unless your doctor tells you to do so.

**Rare** (may affect up to 1 in 1,000 people)
- fever and chills, headache, aching muscles (flu-like symptoms) and generally feeling unwell
- any changes to your skin, for example ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes), widespread blisters or peeling
- serious hypersensitivity reactions involving fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder).
- bleeding in the lips, eyes, mouth, nose or genitals.

**Other side effects:**

**Common** (may affect up to 1 in 10 people)
- skin rash
- Increased level of thyroid stimulating hormone in the blood.

**Uncommon (may affect up to 1 in 100 people)**
- feeling sick (nausea) or being sick (vomiting)
- abnormal liver tests.
- diarrhoea

**Rare** (may affect up to 1 in 1,000 people)
- liver problems such as liver inflammation.

**Very rare** (may affect up to 1 in 10,000 people)
- Occasionally [Nationally completed name] tablets may affect your blood, which can manifest as bruising more easily than usual, or you may develop a sore throat or other signs of an infection. These effects usually occur in people with liver or kidney problems. Tell your doctor as soon as possible.
- [Nationally completed name] may affect the lymph nodes
- high temperature
- blood in your urine (haematuria)
- high levels of cholesterol in your blood (hyperlipidaemia)
- a general feeling of being unwell or feeling weak
- weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- headache, dizziness, drowsiness or disturbance of your vision
- chest pain (angina pectoris), high blood pressure or a slow pulse
- male infertility or erectile dysfunction
- enlargement of the breasts, in men as well as women
- a change in your normal bowel habit
- a change in taste
- cataracts
- hair loss or discolouration
- depression
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- buildup of fluid leading to swelling (oedema) particularly of your ankles
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to check if this is happening.

**Not Known** (cannot be estimated from available data)
- aseptic meningitis (inflammation of the membranes that surround the brain and spinal cord): symptoms include neck stiffness, headache, nausea, fever or consciousness clouding. Seek medical attention immediately if these occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please

tell your doctor or pharmacist.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store [Nationally completed name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.

HDPE bottles: after first opening, use within 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What [Nationally completed name] contains**

- The active substance is allopurinol.
Each tablet contains 100 mg of allopurinol.
Each tablet contains 300 mg of allopurinol

- The other ingredients are lactose monohydrate, maize starch, povidone and magnesium stearate.

**What [Nationally completed name] looks like and contents of the pack**

**[Nationally completed name] 100 mg tablets**

White to off white, scored, flat cylindrical tablet debossed with ‘I’ and ‘56’ on either side of the break line on one side and plain on other side. Diameter: approx. 8 mm.

[Nationally completed name] 100 mg tablets is available in PVC/Alu blisters with pack sizes 20, 30, 50, 60, 100 tablets and 30 x 1 tablets unit-dose or HDPE bottles with PP child resistant cap or PP non-child resistant cap with induction seal, with pack sizes 50, 100, 105, 125, 250, 500 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
**Houder van de vergunning voor het in de handel brengen**
Sandoz B.V.
Veluwezoom 22
1327 AH Almere
Nederland

**Fabrikant**
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
Sachsen-Anhalt, 39179 Barleben
Duitsland

**In het register ingeschreven onder:**
Allopurinol Sandoz tablet 100 mg, tabletten - RVG 117525
Allopurinol Sandoz tablet 300 mg, tabletten - RVG 117526

**Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:**

| | |
|---|---|
| Finland: | Allopurinol Sandoz 100 mg/300 mg tabletit |
| België: | Allopurinol Sandoz 100 mg/300 mg tabletten |
| Bulgarije: | ЛОДИРИК 100 mg/300 mg таблетки |
| Tsjechië: | Alopurinol Sandoz 100 mg/300 mg |
| Denemarken: | Allopurinol Sandoz 100 mg/300 mg tabletter |
| Estland: | Allopurinol Sandoz/Allopurinol Sandoz |
| Spanje: | Alopurinol Sandoz 100 mg/300 mg comprimidos EFG |
| Hongarije: | Allopurinol Sandoz 100 mg/ 300 mg tabletta |
| Letland: | Allopurinol Sandoz 100 mg/300 mg tabletes |
| Nederland: | Allopurinol Sandoz tablet 100 mg/300 mg, tabletten |
| Noorwegen: | Allopurinol Sandoz/Allopurinol Sandoz |
| Polen: | ARGADOPIN/ARGADOPIN |
| Portugal: | Alopurinol Sandoz/Alopurinol Sandoz |
| Roemenië: | Alopurinol Sandoz 100 mg/300 mg comprimate |
| Zweden: | Allopurinol Sandoz 100 mg/300 mg tabletter |
| Slovenië: | Alopurinol Sandoz 100 mg/300 mg tablete |
| Slowakije: | Alopurinol Sandoz 100 mg/300 mg |

**Deze bijsluiter is voor het laatst goedgekeurd in december 2021.**