

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Alloril® Tablets 100 mg, 300 mg

Alloril 100: Each tablet contains 100 mg Allopurinol.

Alloril 300: Each tablet contains 300 mg Allopurinol.

Inactive ingredients and allergens in the medicine –see section 6 "Additional Information" and section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their medical condition seems to be similar.

1. What is the Medicine Intended for?

For the treatment of gout attacks and other conditions related to an excess of uric acid in the body, by reducing the concentration of uric acid in the blood and urine.

Therapeutic group: An inhibitor of xanthine oxidase, the enzyme responsible for uric acid production.

2. Before Using the Medicine

Do not use the medicine if:

You are hypersensitive (allergic) to the active ingredient (allopurinol) or to any of the additional ingredients that this medicine contains (see section 6).
If you are not sure, consult your doctor or pharmacist before taking Alloril.

Special warnings regarding the use of this medicine:

Before treatment with Alloril tell your doctor if:

- you are of Han Chinese, African or Indian origin.
- you have liver or kidney problems. Your doctor may prescribe a lower dosage for you or ask you to take the medicine less often than every day. Your doctor will also monitor your condition more closely.
- you have heart problems or high blood pressure and you take diuretics and/or medicines called ACE-inhibitors (angiotensin-converting-enzyme inhibitors).
- you are currently having a gout attack.
- you have thyroid problems.

Take special care while taking the medicine:

- Serious skin rashes (hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported in patients taking allopurinol. Frequently, the rash can be accompanied by ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by flu-like symptoms: fever, headache, body ache. The rash may progress to widespread blistering and peeling of the skin. These serious skin reactions can be more common in people of Han Chinese, Thai or Korean origin. Additionally, chronic kidney disease may increase the risk in these patients. If you develop a rash or these skin symptoms, **stop taking this medicine and contact your doctor immediately**. Also see section 4 "Side Effects".
- If you have cancer or Lesch-Nyhan syndrome the amount of uric acid in

your urine may increase. To prevent this, you need to be sure to drink sufficiently to dilute your urine.

- If you have kidney stones, they may become smaller and may enter your urinary tract.

Children:

This medicine is rarely administered to children, except in some types of cancer (especially leukaemia) and certain enzymatic disorders (such as Lesch-Nyhan syndrome).

Drug interactions:

If you are taking or if you have recently taken any other medicines, including non-prescription drugs and dietary supplements, tell your doctor or pharmacist, since Alloril may affect the way some medicines work. Also, other medicines may affect the way Alloril works.

Inform your doctor or pharmacist especially if you are taking:

- aspirin, salicylates.
- theophylline, used to treat breathing problems.
- medicines used to treat seizures (epilepsy), phenytoin.
- vidarabine, used to treat herpes or chickenpox.
- antibiotics (ampicillin or amoxicillin).
- didanosine, used to treat HIV infection.
- medicines used to treat cancer (such as 6-mercaptopurin)
- medicines used to reduce your immune response (such as: azathioprine, cyclosporine).
- medicines used to treat diabetes (chlorpropamide).
- medicines used to treat heart problems or high blood pressure such as ACE-inhibitors or diuretics (such as thiazides).
- medicines used to thin your blood (anticoagulants), such as warfarin.
- other medicines used to treat gout (such as probenecid).

If aluminum hydroxide is taken concomitantly, allopurinol may have a weakened effect. Wait at least 3 hours between taking the two medicines.

When taking allopurinol and cytostatic medicines (e.g., cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halides), blood dyscrasias occur more frequently than when these active substances are taken alone.

Therefore, blood count monitoring should be performed at regular intervals.

Use of this medicine with food:

Take the medicine after a meal (also see section 3 "How to use this medicine").

Pregnancy, breastfeeding and fertility:

Consult your doctor before taking this medicine if you are pregnant, might become pregnant or are breastfeeding.
Allopurinol is secreted in breast milk. Taking allopurinol while breastfeeding is not recommended.

Driving and use of machinery:

Use of this medicine may cause drowsiness, dizziness or coordination problems. In these cases, do not drive or use machines.
Children must be warned not to ride a bicycle or play near roads etc.

Important information about some of the ingredients of this medicine:

Alloril contains lactose. If you have been told in the past by your doctor that you have an intolerance to some sugars, consult your doctor before starting treatment with this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per caplet, that is to say essentially "sodium free".

3. How to Use This Medicine

Always use this medicine according to your doctor's instructions. You must check with your doctor or pharmacist if you are not sure of the dosage and the manner of treatment with the medicine.

Dosage and administration are to be determined by the doctor only. The usual recommended dosage is 100-800 mg each day. You will usually start on a low dosage, which will be increased if necessary.
If you are an older person or if you have poor liver or kidney function, your doctor may prescribe a lower dosage or instruct you to take the medicine at longer intervals. If you undergo dialysis two or three times a week, your doctor may prescribe a dosage of 300 or 400 mg to be taken immediately after your dialysis.

The dosage regimen in children (under the age of 15) is calculated according to body weight. The maximum dosage is 400 mg per day.

Do not exceed the recommended dose.

How to take the medicine:

Take the medicine after the meal with a glass of water.

Alloril 100: Do not halve due to lack of score-line. There is no information regarding crushing or chewing.

Alloril 300: Can be halved. There is no information regarding crushing or chewing.

If you accidentally took a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you. Signs of an overdose can include: nausea, vomiting, diarrhoea and dizziness.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, take a dose as soon as you remember. However, if it is almost time for your next dose, skip the forgotten dose. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

Like all medicines, using Alloril can cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Hypersensitivity

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):
If you have a hypersensitivity (allergic) reaction, **stop taking Alloril and see a doctor immediately**.

The symptoms can include:

- flaking skin, blisters or soreness in the lips and mouth.
- very rarely signs can include sudden wheezing, fluttering or tightness in the chest, and collapse.

Rare side effects (effects that appear in 1-10 out of 10,000 users):

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

Very rare side effects (effects that appear in less than one out of 10,000 users):

- severe allergic reaction that causes swelling of the face or throat.
- Potentially life-threatening severe allergic reaction.

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

Additional side effects:

Common side effects (effects that appear in 1-10 out of 100 users):

- Skin rash.
- Increase in the level of thyroid stimulating hormone (TSH) in the blood.

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):
nausea or vomiting, abnormal liver function tests.

Rare side effects (effects that appear in 1-10 out of 10,000 users):

- liver problems, such as liver inflammation.

Very rare side effects (effects that appear in less than one out of 10,000 users):

- occasionally the medicine may affect your blood, which can manifest as a higher-than-usual tendency toward bruising, or you could 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.
- the medicine may affect the lymph nodes.
- high temperature.
- blood in your urine (hematuria).
- high levels of cholesterol in your blood (hyperlipidemia).
- a general feeling of illness or weakness.
- weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness.
- headache, dizziness, drowsiness or vision disturbances.
- 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 activity, changes in taste.
- cataract.
- hair loss or discolouration.
- depression.
- lack of coordination of voluntary muscle movements (ataxia).

- sensation of tingling, tickling, pricking or burning of the skin (paraesthesia).
- build-up 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.

If you experience a side effect, or if one of the side effects worsens or when you suffer from any side effect not listed in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form for adverse events reporting, or via the following link: <https://sideeffects.health.gov.il>

5. How to Store the Medicine

- Avoid poisoning! Store this medicine and all other medicines in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store at a temperature below 25°C.
- Do not throw disposed of medicines via wastewater or household waste. Return tablets no longer in use or unwanted tablets to the pharmacist for disposal. You must keep the tablets only if your doctor tells you to. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Lactose monohydrate, Maize starch, Sodium starch glycolate, Hypromellose, Glycerol, Povidone, Magnesium stearate, Titanium dioxide, Macrogol 400, Carnauba wax.

What the medicine looks like and contents of the pack:

Alloril 100: white, round, coated tablets, convex on both sides.

Alloril 300: white, round, coated tablets, convex on both sides, scored on one side.

Approved pack sizes:

Alloril 100: 10, 50, 100, 1000 tablets.

Alloril 300: 10, 20, 30, 50, 100, 1000 tablets.

Not all pack sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health in: February 2017 and updated in accordance with the Ministry of Health instructions in June 2019.

Drug registration number at the national medicines registry of the Ministry of Health:

Alloril 100: 039-76-26038-00

Alloril 300: 039-74-26039-00

PIL Alloril PB0819-07

Manufacturer and registration holder: **Dexcel® Ltd.**

1 Dexcel St., Or Akiva 3060000, Israel