For Patient

Otsuka



Fictional patient

Your guide to JINARC® (tolvaptan)

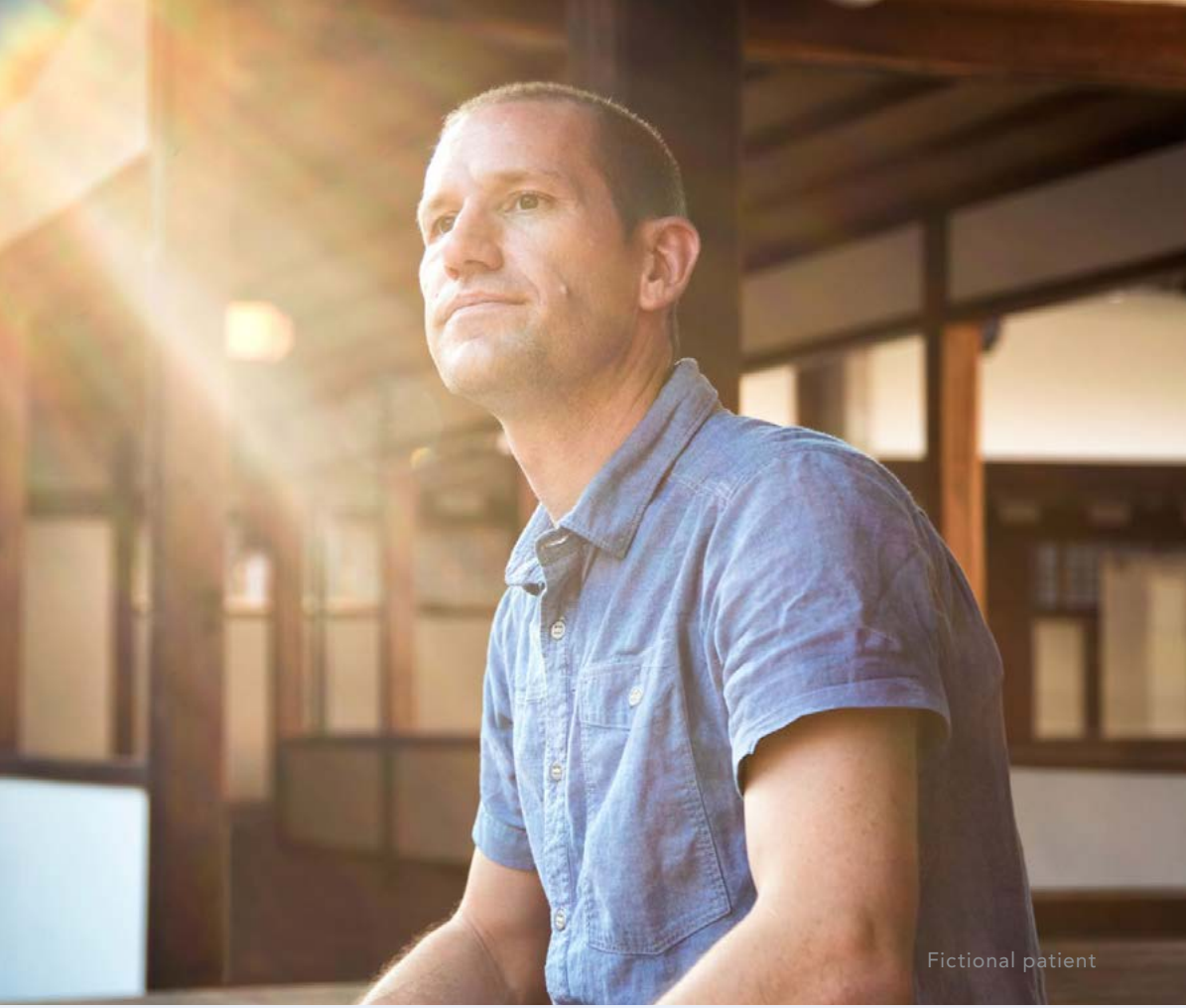
Contents

About this guide 3
How JINARC® works in people with ADPKD 4
The relationship between cysts, kidney size and kidney function in ADPKD 4
ADPKD and the role of vasopressin in cyst growth 5
JINARC® and vasopressin 5
Before starting JINARC® 6
Steps for starting and continuing treatment with JINARC® 8
Important information to tell your doctor 10
Pregnancy and breastfeeding 12
JINARC® and other medicines 12
Taking JINARC® 13
JINARC® dosing 13
How to take JINARC® 14
Missed doses 15
If you take too much 15
Importance of adherence 16
Water intake and elimination (urination) 16
Other potential side effects 17
More information 18



This guide is only intended for people who have been prescribed JINARC® for ADPKD and should be read in conjunction with the Consumer Medicine Information (CMI). Refer to page 18 for more information.

This guide is not intended to replace professional medical advice and should you require further information about JINARC® or ADPKD, please speak with your healthcare team.



About this guide

This guide provides important information to support you while taking JINARC® (tolvaptan). It will help you:

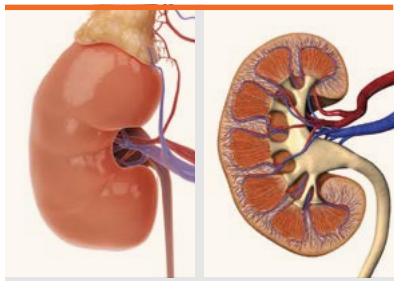
- Understand the role of JINARC® in autosomal dominant polycystic kidney disease (ADPKD)
- Take JINARC® as prescribed
- Recognise potential side effects of treatment
- Complete your regular monitoring appointments as required

How JINARC® works in people with ADPKD

The relationship between cysts, kidney size and kidney function in ADPKD

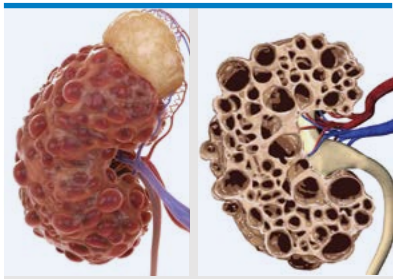
Autosomal dominant polycystic kidney disease (ADPKD) is a common inherited kidney disease. In ADPKD, cysts, which are sacs filled with fluid, form in the kidneys. When this happens, the affected parts of the kidney are often no longer able to function properly.

In ADPKD, cysts usually develop on both kidneys. Over time, more cysts develop, individual cysts get bigger, and some will eventually burst. Some people experience symptoms of disease progression such as kidney pain.



Healthy kidneys

- No cysts or very few
- Tubules are open to drain urine into the bladder (through ducts)
- Kidneys are about the size of a fist



Kidney with polycystic kidney disease (PKD)

- Cysts develop throughout the kidney; they increase in number and size as disease progresses
- Some tubules are blocked by cysts
- Kidneys get larger as disease progresses

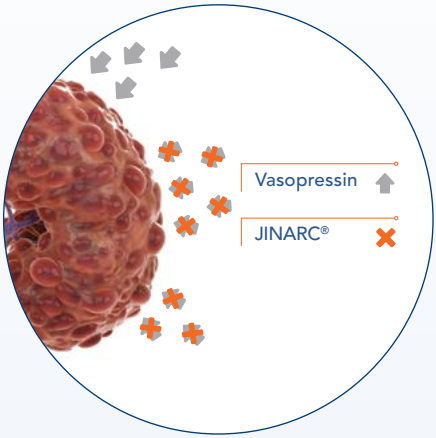
Even if you do not yet have symptoms, if you have ADPKD, cysts are continually forming and growing on your kidneys.

As the cysts continue to grow in number and size, the kidneys get larger and have a harder time doing their job. Eventually, they may stop working altogether.

ADPKD and the role of vasopressin in cyst growth

To filter waste and water out of your blood, your kidneys use a hormone called vasopressin. Vasopressin makes the kidneys retain water.

Vasopressin levels are higher than normal in people with ADPKD. The high level of vasopressin in people with ADPKD promotes cyst growth, which increases the size of the kidneys.



JINARC® and vasopressin

JINARC® is a medicine for the treatment of ADPKD and works by blocking the effects of vasopressin. By blocking vasopressin, JINARC® should help slow down the rate at which cysts grow.

Because of the way that JINARC® works, you may produce more urine causing you to urinate more frequently during the day and night. This may become less pronounced over time, but speak with your healthcare team for advice on how to manage this effect.

Before starting JINARC®

Some patients taking JINARC® have experienced changes in liver function that could be a sign of a liver injury. To reduce the risk, regular blood tests are required before starting and during treatment with JINARC®.

Your doctor will discuss all the potential risks and benefits of JINARC® with you before you are prescribed JINARC®.

JINARC® may cause your liver to not work properly. Therefore, please inform your doctor immediately if you have any signs that could indicate potential liver problems, such as:

- Nausea
- Vomiting
- Fever
- Tiredness
- Loss of appetite
- Pain in the abdomen
- Dark urine
- Jaundice (yellowing of the skin or eyes)
- Itching of your skin
- Joint and muscle pain with fever

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

Required blood testing

When	Frequency of blood tests
Prior to starting treatment	Once
First 18 months of treatment	Monthly
After 18 months of treatment	Every 3 months

Education Materials

You can contact the medical information department to receive an electronic version of this booklet, the JINARC® Consumer Medicine Information (CMI) and Wallet Card.

You should carry the Wallet Card with you at all times to alert other members of your healthcare team about your treatment with JINARC®.

1800 059 606
OAPMedical@au.otsuka.com

The Patient Guide and Wallet Card are also available via the products page of the Otsuka Australia website at ***otsuka.com.au***

Important tips to remember

1 It's best to continue using the same pharmacy as JINARC® is a specialty product and the pharmacist can make sure JINARC® is available when you need it.

2 Complete your blood tests monthly for the first 18 months, and then every 3 months thereafter.

3 If your blood test results are normal, place your JINARC® order with your nominated pharmacy.

4 If your blood test results are abnormal, your doctor will contact you to discuss your treatment plan.

Steps for starting and continuing treatment with JINARC®

1

Review the potential risks and benefits of JINARC® treatment with your doctor and discuss the need for regular blood tests

2

Ensure you have had a liver function test before you start JINARC®


3
Take your prescription to your pharmacy to collect JINARC®
4
Take JINARC® twice a day as prescribed by your doctor
5
Get your liver function tests:
• Every month for the first 18 months
• Every 3 months afterwards, for as long as you stay on treatment

Important information to know before starting JINARC®

Do not use JINARC® if:

- You are allergic to tolvaptan, benzazepine derivatives or any of the ingredients listed in the CMI under 'Product Details'
- You have been told that you have raised levels of liver enzymes in your blood
- You have high level of sodium in your blood
- You do not realise when you are thirsty
- Your kidneys cannot produce urine
- You have low blood volume
- You are pregnant
- You are breastfeeding
- You are below the age of 18 years



Before starting JINARC®, check with your doctor if you:

- Have any other medical conditions
- Take any medicines for any other condition
- Cannot drink enough water, are fluid restricted
- Are dehydrated or suffer from excessive vomiting, diarrhoea or sweating
- Have difficulties in urination or have an enlarged prostate
- Suffer from liver disease
- Suffer from too high or too low blood sodium
- Suffer from high potassium levels in your blood
- Have diabetes
- Have high blood pressure and are taking medications to treat it
- Have gout
- Are pregnant or breastfeeding
- Have lactose intolerance

Pregnancy and breastfeeding

Before and while taking JINARC®, you must:

- Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding. JINARC® must not be taken if you are pregnant or while breastfeeding.
- Tell your doctor immediately if you become pregnant. Your doctor will advise you on whether you should stop treatment.
- Use a reliable method of contraception to avoid becoming pregnant. You should continue doing this for one month after stopping treatment.

Reliable contraception

Please speak to your doctor about the appropriate contraceptive method for you. There are a number of different methods and it is important to choose one that best meets your needs and circumstances.

Information to share with your healthcare team

You should:

- Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. In particular let your doctor know if you are taking any of the medications listed in the 'What if I am taking other medicines?' section of the CMI.
  It may still be alright for you to take these medicines and JINARC® together. Your doctor will be able to decide what is suitable for you.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking JINARC®.
- Tell any surgeon or anaesthetist that you are taking JINARC® if you are going to have surgery.
- Tell your doctor if you drink alcohol.

Refer to Consumer Medicine Information (CMI)

Taking JINARC®

While you are taking JINARC®, you should follow all directions given to you by your healthcare team carefully. They may differ from the information contained in this guide.

JINARC® dosing

JINARC® is taken twice a day. Each JINARC® tablet has a different amount of medicine. The two tablets you take each day add up to your total daily dose. The first dose of the day is always higher than the second dose. This gives you the best balance between the amount of medicine in your body and possible increased urination at night.

Your doctor will prescribe one of three total daily doses shown in the table below. Your doctor may adjust your dose in the first weeks or months of treatment to help find the best dose for you. Take your prescribed dose as shown; however, **if you take other medicines that increase the effects of JINARC®, your doctor may prescribe you a lower dose than shown below.**

JINARC® dose combinations

Total daily dose (your doctor will decide which dose is right for you)	**First daily dose** (take upon waking and at least 30 minutes before eating)	**Second daily dose** (8 hours after first dose and taken with or without food)
60 mg	45 mg	15 mg
90 mg	60 mg	30 mg
120 mg	90 mg	30 mg

How to take JINARC®



When taking JINARC® you should:

- ✓ **Swallow the tablets whole without splitting, chewing or crushing the tablets, with a glass of water**
- ✓ **Take the first daily dose at least 30 minutes before eating**
- ✓ **Take the second daily dose approximately 8 hours after the first daily dose, with or without food**
- ✓ **Take your medicine at about the same time each day**
- ✓ **Drink plenty of water**
- × **NOT drink grapefruit juice while you are on JINARC® treatment**

Missed doses

If you forget to take your medicine you should take the dose as soon as you remember on the same day.

If you do not take your tablets on one day, take your normal dose on the next day. DO NOT take a double dose to make up for forgotten individual doses.

Other important information

Do not give your medicine to anyone else, even if they have the same condition as you.

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

If you take too much

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much JINARC®. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Importance of adherence

While taking JINARC®, it is important that you:

- Continue taking your medicine for as long as your doctor tells you
- Do not stop unless your doctor advises you to
- Do not change the dose without checking with your doctor
- Speak with your healthcare team for help to stay on treatment if the effects of thirst and/or urination are causing you problems
- Do not take JINARC® to treat any other complaints unless your doctor tells you to

Water intake and elimination (urination)

Water intake

As an ADPKD patient, you may already know that it is important to drink plenty of water every day. This is also extremely important when you are on JINARC®.

Water loss may result in side effects such as dry mouth and thirst or even more severe side effects like kidney problems. It is therefore important that you have access to water and that you are able to drink sufficient amounts when you feel thirsty.

To prevent dehydration, make sure you have water available to drink at all times while you are on JINARC®. Unless your healthcare team tells you otherwise, you should:

- ✓ **Drink plenty of water during the day or in response to thirst**
- ✓ **Drink 1–2 glasses of water before bedtime, even if you are not thirsty**
- ✓ **Drink water after you urinate at night**

Certain medicines or illnesses may keep you from drinking fluids or may cause you to lose too much body fluid, such as excessive vomiting, diarrhoea or sweating. If you have these problems, call your healthcare team right away.



Water elimination (urination)

Because of the way JINARC® works, you are likely to experience thirst, increased amount of urine and/or increased frequency of urination, including at night.

JINARC® can cause approximately 5-7 litres of urine to be produced per day.

Talk to your healthcare team to understand how to best manage these side effects, if you have them.

Other potential side effects

JINARC®, like any other medicine, can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking JINARC®.

For more information on the potential side effects of this medication, please read the CMI or speak with your healthcare team.

Common side effects include thirst; increased amount and frequency of urination; headache; constipation, diarrhoea, dry mouth, indigestion, decreased appetite; fatigue, weakness, dizziness; trouble sleeping; muscle spasms; rash, dry skin, itching; painful, swollen joints. Serious side effects include difficulty urinating; swelling of the face, lips or tongue, generalised rash, or severe wheezing or breathlessness; signs of electrolyte imbalances.

JINARC® may cause side effects that can affect your ability to drive or use machines.

JINARC® may make you feel dizzy or sleepy, particularly at the beginning of treatment. If this happens to you, do not drive or use any tools or machines.

More information

The JINARC® Consumer Medicine Information (CMI) leaflet is available at:

Scan QR code or visit **https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-CMI-01215-1**

or by calling **1800 059 606**

If you require more information about your disease or JINARC® treatment, please speak with your healthcare team.

For further information

Australia Toll Free: 1800 059 606

Notes

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Date of preparation: August 2026. JIN-AU-495.