

YOUR GUIDE TO UNDERSTANDING, BEGINNING AND CONTINUING TREATMENT WITH Pr JINARC®



For **autosomal dominant polycystic kidney disease** (ADPKD)



A GUIDE TO HELP YOU GET STARTED WITH

Pr **JINARC**^{MD}

This guide is for people with ADPKD who have been prescribed JINARC (tolvaptan). It was written to help you discuss the potential benefits and risks of JINARC with your doctor. To help you get the most out of your treatment, this guide also explains how JINARC works, possible side effects and how it should be taken.

This guide does not replace the advice of a healthcare professional. Be sure to discuss your disease, your treatment, and any questions you have with your healthcare team.

WHAT YOU'LL FIND INSIDE

Page 4 How Pr JINARC® works in ADPKD patients

Page 6 Before starting JINARC

Page 8 Taking JINARC

Page 9 Possible side effects, and the importance of adherence

Page 13 Get more with ORIJIN®: Your value-added support program, available for JINARC patients

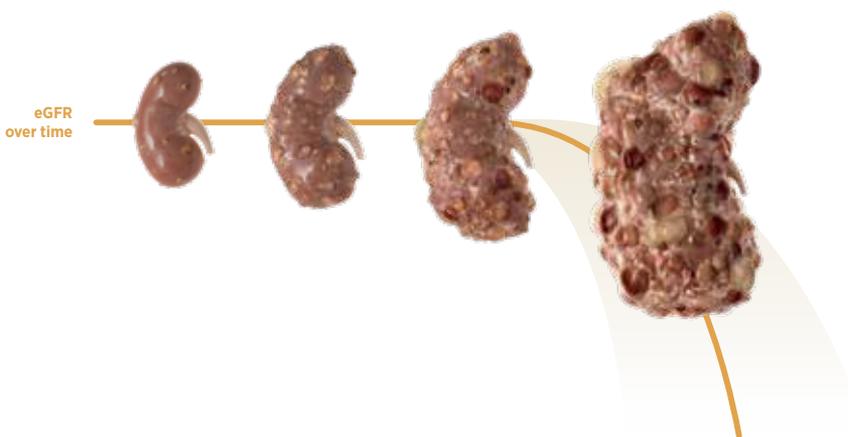
Page 14 Steps to starting and continuing on JINARC



HOW ^{Pr}JINARC® WORKS IN ADPKD PATIENTS

What is ADPKD?

In order to understand how JINARC works, we have to first understand ADPKD. ADPKD is a progressive, genetic disorder characterized by the formation of multiple cysts (sacs with fluid) on the kidneys.



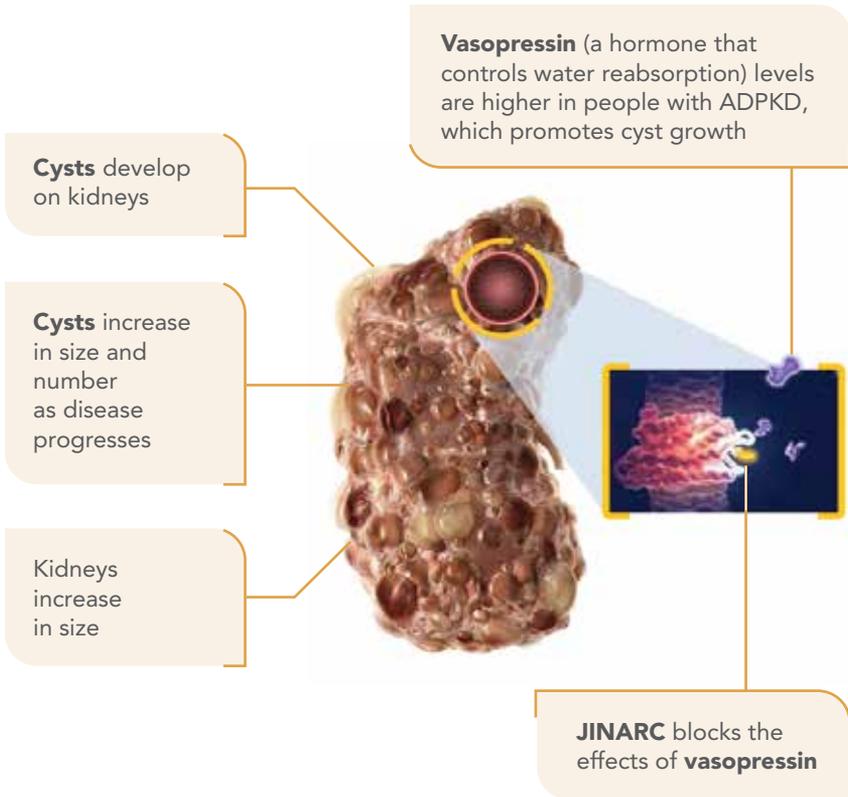
- Cysts grow in number and size and can damage kidney function
- Even if cysts are forming or growing, symptoms of ADPKD may not be present
- Symptoms of ADPKD can vary greatly, even among members of the same family
- Slowing down disease progression can help manage symptoms of ADPKD

Here are some important facts to remember about ADPKD:

- A genetic disorder that can be inherited from either parent
- It can lead to kidney failure
- Disease progression varies per person
- 1 in 400 – 1,000 people can have ADPKD

You may have been living with ADPKD for most of your life, or you could have been recently diagnosed. In any case, you can start managing your ADPKD with JINARC.

How does PrJINARC® work?



JINARC slows cyst growth and the decline of kidney function which should help protect the kidneys from damage and failure

Because of the way JINARC works, you will urinate more frequently during the day and night. This effect will be less pronounced over time.

BEFORE STARTING Pr JINARC®

For your safety: The JINARC Controlled Hepatic Safety Monitoring and Distribution Programme

In rare cases, JINARC patients have experienced changes in liver function that could, if left untreated, cause liver injury. To reduce this risk, you must agree to get regular blood tests, and you must enroll in the JINARC Hepatic Safety Monitoring and Distribution (HSMD) Programme.

The HSMD Programme was designed to monitor liver function so as to ensure it is within normal limits, so that you can stay on treatment. The HSMD Programme does this by making sure that you have a blood test:

- **before** you start JINARC
- **every month** for the first 18 months, then
- **every 3 months** for the next 12 months, and
- **every 3-6 months** afterwards, as long as you stay on treatment

The HSMD Programme can remind you when it's time for you to go for a blood test. This is important because your doctor will need to review your blood test results and provide their approval before you can receive your next refill of JINARC.

Your doctor will discuss the HSMD Programme with you before you are prescribed JINARC.

Confirming your understanding: The Patient-Prescriber Agreement Form (PPAF)

Your doctor will review all the potential risks and benefits of JINARC with you before prescribing JINARC. If you both agree that JINARC is appropriate for you, you and your doctor must sign a Patient-Prescriber Agreement Form (PPAF). Signing the PPAF means that:

- you understand the potential risks, especially for the liver, and the benefits that may occur over time when receiving treatment with JINARC
- you and your doctor agree that JINARC is suitable for you
- you agree to take your regular blood tests
- you agree to start treatment

In order to gather information on the long-term clinical outcomes with JINARC, your doctor may discuss with you the possibility to participate in the Canadian JINARC Patient Outcomes Registry.

For more information, contact Otsuka MedInfo at 1-877-341-9245.

Who should not take Pr JINARC®

You should not take JINARC if:

- you have been asked to permanently discontinue tolvaptan
- you are allergic to tolvaptan, benzazepine or benzazepine derivatives (e.g., REMERON®), or any non-medicinal ingredients in the formulation
- you cannot replace fluids by drinking or you cannot feel if you are thirsty
- you have elevated sodium (salt) in your blood
- you have a condition associated with a low blood volume
- your liver is not functioning properly and in a way that is of concern to your doctor
- you are pregnant or plan to become pregnant, or are breastfeeding
- your body is not able to make any urine
- you take certain medicines. Here are examples of medicines that could cause you to have too much JINARC in your blood:
 - Clarithromycin or telithromycin (antibiotic medicines)
 - Ketoconazole or itraconazole (antifungal medicines)
 - Ritonavir, indinavir, nelfinavir, and saquinavir (anti-HIV medicines)
 - Nefazodone (antidepressant medicine)
- you have Galactose intolerance, Lapp lactase intolerance or Glucose-galactose malabsorption (all rare hereditary diseases), because JINARC contains lactose

Pregnancy prevention

To prevent pregnancy while on JINARC treatment, women of childbearing potential must have effective contraceptive measures in place before and during treatment.

JINARC and other medicines

Before starting JINARC, tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, minerals, natural supplements and alternative medicines. Taking JINARC with other medicines may affect the way JINARC works, or the way other medicines work. Your doctor may need to adjust your dose of JINARC or of the other drugs if you take them together.

Before starting any new treatments, tell your healthcare provider that you are on JINARC. In particular, you must tell them before they prescribe any new medications. If you do start any new medications, tell your nephrologist (or the doctor who prescribed JINARC) as soon as possible.

TAKING Pr JINARC®

JINARC dosing

JINARC is taken twice a day. Each JINARC pill has a different amount of medicine. The 2 pills you take each day add up to your total daily dosage.

The first dose of the day is always higher than the second dose. This was designed to give you the best balance between the amount of medicine in your body and possible increased urination at night. Your doctor will usually prescribe one of the 3 total daily doses shown in this table. Your doctor may adjust your dose during the first weeks or months of treatment, to help find the best dose for you. Take your prescribed dose as shown.

Total daily dose (Your doctor will decide which dose is right for you)	AM dose (first thing in the morning)	PM dose (8 hours after your AM dose)
60 mg	45 mg 	15 mg 
90 mg	60 mg 	30 mg 
120 mg	90 mg 	30 mg 

If you are taking certain medicines, your doctor may reduce your usual dose of JINARC. Certain medicines could cause you to have too much JINARC in your blood. Your doctor may reduce your dose to the following:

- 15 mg AM dose + 15 mg PM dose, for a total daily dose of 30 mg **OR**
- 30 mg AM dose + 15 mg PM dose, for a total daily dose of 45 mg

How to take JINARC

- ✓ You can take JINARC with or without food.
- ✗ **Do not drink** grapefruit juice while you are on JINARC.
- ✓ To prevent losing too much body water (dehydration), have water available to drink **at all times** while on JINARC. Unless your healthcare provider tells you otherwise, drink plenty of water during the day, and one or two glasses before going to bed.

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

Except in emergency situations, do not stop taking JINARC without first talking to your doctor.

What to do if you miss a dose

You should not miss or skip doses of ^{Pr}JINARC®. If you do miss a dose, take your next dose at the scheduled time and prescribed level. **Do not take 2 doses at the same time.**

If you are having a hard time remembering to take your JINARC dose, talk to your healthcare team for help incorporating JINARC into your daily schedule.

POSSIBLE SIDE EFFECTS, AND THE IMPORTANCE OF ADHERENCE

Possible side effects during JINARC treatment

As with any medicine, JINARC can cause certain side effects, though not everyone gets them.

Known side effects

The expected side effects of JINARC treatment are thirst, urinating large amounts and/or frequently, and urinating at night.

Other possible side effects include headache, constipation, diarrhea, dry mouth, indigestion, decreased appetite, fatigue, weakness, dizziness, trouble sleeping, muscle spasms, rash or itching, and abdominal pain.

When to talk to your healthcare team

Talk with your doctor, nurse or pharmacist if you experience any of the following:

- **Increased levels of potassium in the blood:** symptoms such as irregular heartbeats, muscle weakness and generally feeling unwell
- **Increased levels of uric acid in the blood/gout:** symptoms such as joint pain, commonly in the big toe, followed by redness, swelling or warmth
- **Liver disorder:** symptoms such as yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting or loss of appetite

You should also talk to your healthcare team if you experience a side effect that distresses you.

Emergency situations

Stop taking Pr JINARC® and get immediate emergency medical help if you have any of the following:

- **Dehydration:** symptoms such as increased thirst, dry mouth and/or skin, fatigue, decreased amount of urine, headache, dizziness or irregular heartbeats
- **Angioedema and severe allergic reactions:** symptoms such as swelling of the face, eyes, or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing or unconsciousness

Water intake and elimination (urination)

Water intake

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

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 throughout the day
- ✗ but **do not drink** grapefruit juice
- ✓ drink 1–2 glasses of water before bedtime, even if you are not thirsty

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

Water elimination (urination)

As discussed above, people on JINARC are likely to experience thirst, urinating large amounts and/or frequently, and urinating at night. This is related to how the medication works.

Work with your healthcare team to find ways that you can adapt to these effects, if you have them.

Adhering to JINARC treatment

You should not stop taking JINARC without talking to your doctor first. If the effects of thirst and/or urination are making it difficult for you to stay on treatment, talk to your healthcare team for help with adapting your daily routine.



PEOPLE ON ^{Pr}JINARC® ARE ENTITLED TO ALL THE BENEFITS OF THE ORIJIN® PATIENT SUPPORT PROGRAM

The ORIJIN Program gives you:

- Dedicated nurses for support to initiate JINARC and help answer questions about treatment
- A personal reimbursement specialist for reimbursement/financial assistance
- Pharmacy services and delivery of JINARC to the patient's home or work
- The Home Bloodwork Program or phone call reminders to go for blood tests
- Liver function tests monitoring
- JINARC.ca, a comprehensive and informative website with pertinent topics and useful tips to guide you through your treatment.
To access JINARC.ca, enter one of the following drug identification numbers (DIN): 02437503, 02437511, 02437538
- Personalized guidance on nutrition, counselling, and advice on optimal dietary management practices through experienced Canadian dietitians with knowledge on ADPKD-related nutrition
- A Co-Pay card for patients with private insurance that includes JINARC coverage. You have access to a pharmacy Co-Pay card which guarantees that you will have no additional cost when you receive JINARC
This program will cover any potential cost differences between JINARC and your private payer plan



Scan to access JINARC.ca

If you have any questions about the ORIJIN Patient Support Program or JINARC, you can reach out to your ORIJIN nurse at 1-844-254-6272 or your JINARC representative.

Keep this card with you at all times in case of emergency or even for a quick inquiry.



Prescriber's name: _____

Phone number: _____

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GET MORE WITH ORIIN®:
YOUR VALUE-ADDED SUPPORT
PROGRAM, AVAILABLE FOR
Pr JINARC® PATIENTS



Only once you are prescribed JINARC, are you eligible for personalized support through the ORIIN Patient Support Program.

As you start and continue on treatment, the ORIIN Program can adapt to your needs in various ways – it's all up to you. For example, the ORIIN Program can help you get started on treatment, set goals, answer questions and get access to additional services throughout your journey.



We'd love to walk you through the other ways ORIIN can provide you with support!

Scan to watch the video

▼ Tear out this card and put it in your wallet.



Your direct line to Pr JINARC® support

1-844-2JINARC
(1-844-254-6272)

STEPS TO STARTING AND CONTINUING ON PrJINARC®

Review the potential risks and benefits of JINARC treatment with your doctor



Complete and co-sign the PPAF (keep a copy for yourself)



Get your liver function tests:

- Before you start JINARC
- Every month for the first 18 months
- Every 3 months for the next 12 months, and
- Every 3-6 months afterwards, as long as you stay on treatment



Receive JINARC from pharmacy, and take it as prescribed by your doctor



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