PRESCRIBER'S GUIDE
GETTING STARTED WITH PrJINARC®

Orijin SUPPORT PROGRAM

PrJINARC® tolvaptan

The ORIJIN-al tolvaptan is JINARC[1]

ORIJIN® is the Patient Support Program for patients on JINARC.

Our unwavering commitment to you and your patients continues.

JINARC is the first treatment indicated in ADPKD.*

Trust in our 10+ years of experience in Canada.†

Your guide to discussing and prescribing JINARC
With the commitment of the ORIJIN team

PrJINARC® (tolvaptan) is indicated to slow the progression of kidney enlargement and kidney function decline in adult patients with autosomal dominant polycystic kidney disease (ADPKD). In ADPKD, kidney enlargement reflects renal cyst burden.[1]

* Comparative clinical significance unknown.
† Clinical significance unknown.

PrJINARC® FOR PATIENTS WITH ADPKD

JINARC is the first treatment indicated to slow the progression of kidney enlargement and kidney function decline in patients with ADPKD. In ADPKD, kidney enlargement reflects renal cyst burden.[1,2]

Increased kidney size and renal cyst burden are indicative of disease progression.[3,4]

About this guide

This guide was written to support you in prescribing JINARC. It will:

- help you identify which patients are best suited for treatment with JINARC
- list the contraindications to JINARC
- clarify the hepatic safety warning
- explain the conditions to use JINARC, including:
  - liver monitoring requirements, and the JINARC Controlled Hepatic Safety Monitoring and Distribution (HSMD) Programme that will support you and your patients with the required, ongoing monitoring
  - the Patient-Prescriber Agreement Form (PPAF) that you and each patient must co-sign as part of the prescription process
- help you review the potential risks and benefits of JINARC with your patients (supporting the full Product Monograph)
- give you an overview of titration and dose adjustments for JINARC, including recommendations regarding concomitant medications

RECOGNIZING APPROPRIATE PATIENTS FOR [Pr]JINARC®

ATTRIBUTES OF PATIENTS WHO CAN BENEFIT FROM JINARC

TEMPO 3:4

- Have rapidly-progressing ADPKD (meeting modified Ravine criteria)
- Are at early stage of CKD
- TKV ≥750 mL
- Estimated creatinine clearance ≥60 mL/min

REPRISE

- Have high risk of progressive eGFR decline based on renal function for age (18 to 65 years of age with baseline eGFR between 25 and 65 mL/min/1.73m^2)

FACTORS ASSOCIATED WITH RAPID PROGRESSION

Large TKV for given age

Presence of systemic hypertension or albuminuria

Rapid deterioration of renal function

CKD Stage 2-3

Patients without evidence of hypertension, and especially those at an early stage of disease with excellent renal function (eCrCl ≥120 mL/min) consistent with compensatory hyperfiltration appear to show little near-term benefit in terms of TKV progression or diminution of renal function decline.

CKD: chronic kidney disease; TKV: total kidney volume.

SELECT WARNINGS AND PRECAUTIONS FOR [Pr]JINARC®

Contraindications

JINARC is contraindicated in:

- Patients who have been asked to permanently discontinue tolvaptan
- Patients with known or suspected hypersensitivity to tolvaptan, benzazepine or benzazepine derivatives (e.g., mirtazapine) or any of the excipients
- Patients with hypovolemia
- Patients with hypernatremia
- Patients with anuria
- Patients who do not have access to fluids or who cannot respond to the physiologic sensation of thirst
- Patients with a history, signs or symptoms of significant liver impairment or injury, excluding uncomplicated polycystic liver disease
- Patients using strong CYP3A inhibitors, e.g., ketoconazole, itraconazole, clarithromycin, telithromycin, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone
- Pregnancy
- Nursing women
- Patients with one of the following rare hereditary diseases: galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption

Warning: Idiosyncratic hepatic toxicity

PrJINARC® use has led to idiosyncratic elevations of blood alanine and aspartate aminotransferases (ALT & AST), rarely associated with concomitant elevations of total bilirubin. To help mitigate the risk of liver injury, blood testing for hepatic transaminases and total bilirubin is required prior to initiation of JINARC, then blood testing for hepatic transaminases is required:

- monthly for 18 months
- every 3 months for the next 12 months
- every 3–6 months thereafter during treatment with JINARC

Therefore, JINARC is available for treatment of patients with ADPKD only through a controlled hepatic safety monitoring and distribution programme conducted and maintained by, or for, the market authorization holder of JINARC.

In TEMPO 3:4, a double-blind, randomized, placebo-controlled trial in patients with ADPKD (N=1,445; n=961 tolvaptan), 2 (2/957, 0.2%) tolvaptan-treated patients as well as a third from an open-label extension trial exhibited increases in hepatic enzymes (>3x upper limit of normal [ULN]) with concomitant elevations in total bilirubin (>2x ULN) when monitoring for liver enzymes elevation was every 3–4 months. These concomitant elevations were gradually reversible with prompt discontinuation of tolvaptan; however, they represent a potential for significant liver injury.

In REPRISE, a double-blind, randomized, placebo-controlled trial in patients with later stages of ADPKD (N=1,519; n=1,370 randomized; n=683 randomized to tolvaptan), all patients were monitored monthly for liver enzymes elevation and none of them showed this concomitant level of hepatic enzyme and bilirubin elevation.

This suggests that monthly liver function monitoring during treatment helps detect liver enzyme elevation early on.

In post-marketing experience with tolvaptan in ADPKD, acute liver failure requiring liver transplantation has been reported.

Regular monitoring helps mitigate the risk of significant and/or irreversible liver injury. Concurrent monitoring for symptoms that may indicate liver injury (e.g., fatigue, anorexia, nausea, upper right abdominal discomfort, vomiting, fever, rash, pruritus, icterus, dark urine or jaundice) is also warranted.

Actions for abnormal results

At the onset of symptoms or signs consistent with hepatic injury, or if abnormal ALT or AST increases are detected, [Pr]JINARC® administration must be immediately interrupted and liver function tests (LFTs) – i.e., ALT, AST, total bilirubin, alkaline phosphatase – must be obtained as soon as possible, ideally within 48–72 hours. Testing should continue at an increased frequency until symptoms/signs/laboratory abnormalities stabilize or resolve, at which point cautious reinitiation of JINARC may be considered.

Current clinical practice suggests that JINARC treatment should be immediately interrupted upon confirmation of sustained or increasing transaminase levels, and permanently discontinued if significant increases and/or clinical symptoms of hepatic injury persist. Recommended guidelines for permanent discontinuation include:

- ALT or AST >8-times ULN
- ALT or AST >5-times ULN, for more than 2 weeks
- ALT or AST >3-times ULN, **and** total bilirubin >2x ULN or international normalized ratio (INR) >1.5
- ALT or AST >3-times ULN, with persistent symptoms of hepatic injury as noted above

Permanent discontinuation from receiving tolvaptan is a contraindication, and so once a patient has been permanently discontinued from receiving tolvaptan, treatment must **never be** restarted. The permanent discontinuation status of patients should be verified prior to initiation with tolvaptan.

Pregnancy prevention and other cautions and precautions

- Women of childbearing potential must be advised to use highly effective contraceptive measures prior to and during [Pr]JINARC® use.
- Highly effective contraception is a method of birth control which results in a low failure rate (i.e., less than 1% per year) when used consistently and correctly.
- JINARC use is contraindicated in pregnant and nursing women.

For women of childbearing potential, the nurses at the ORIJIN® Patient Support Program will ensure that:

- A negative serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL is obtained within 1 week prior to beginning treatment with JINARC
- The negative pregnancy test is obtained for every new patient
- They answer all of the patients' questions on pregnancy and nursing

The ORIJIN Patient Support Program: Experienced, Established and Engaged.

Please read the Product Monograph for full information regarding dehydration, concomitant use of CYP3A inhibitors or inducers, P-gp inhibitors, hepatotoxicity, hypernatremia, hyperkalemia, hyperuricemia, hypotension-related events, serum sodium abnormalities, hepatic impairment, and renal impairment.

PrJINARC® CONDITIONS OF USE

The JINARC Controlled Hepatic Safety Monitoring and Distribution (HSMD) Programme

The manufacturer of JINARC has implemented a safety monitoring initiative with regard to the use and access to JINARC. This initiative is called the JINARC HSMD Programme. All prescribers and patients must take part in the HSMD Programme in order to prescribe/receive JINARC in Canada.

The HSMD Programme facilitates blood testing and results confirmation between the patient, the pharmacy and you, to support long-term monitoring and safety. The HSMD Programme will follow up with you for every required test, to find out if the test was done and to confirm the result (ALT or AST ≤3-times ULN). The HSMD Programme supports you in reminding patients to go for their blood tests, and will distribute JINARC to the patient's pharmacy when the monitoring conditions (e.g., blood tests) are met.

For an overview of how the HSMD Programme works, see the diagram on the next page.

Who can prescribe JINARC

JINARC should be initiated and monitored under the supervision of a nephrologist or specialist with expertise in the management of patients with ADPKD and a full understanding of the benefits and risks of tolvaptan therapy including hepatic toxicity and monitoring requirements.

Online support education

The manufacturer of JINARC recommends that you and all other members of the ADPKD management team complete the online training module: *JINARC Educational Training Module*.

The module is available at JINARC.CA.

The Patient-Prescriber Agreement Form (PPAF)

The prescription process for PrJINARC® requires that you and each patient together review and co-sign a PPAF. The purpose of the PPAF is to document the fully-considered engagement of both the patient and the prescriber to the treatment of ADPKD with JINARC.

JINARC can only be prescribed to patients who have completed and signed the PPAF with the prescriber. The form must be signed by the prescriber and the patient in person, and at the same time.

Before asking the patient to sign the form, careful consideration and discussion of the appropriateness of JINARC treatment should be undertaken between the prescriber and patient, taking into account the potential risks and benefits of treatment, appropriate patient selection, and the need for mandatory ongoing hepatic function monitoring.

Once the PPAF has been signed, the prescriber and patient should each keep a copy.

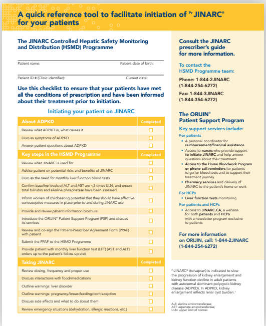
The Canadian JINARC Patient Outcomes Registry

In order to enhance the continuous evaluation of the long-term effects of tolvaptan in ADPKD, all patients to be initiated on JINARC should be offered participation in the manufacturer and product-specific Canadian JINARC Patient Outcomes Registry.

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

Initiating JINARC for your patients

The HSMD Programme/Nurse checklist was created to facilitate initiation of JINARC. The checklist is meant to ensure your patients have met all the conditions of prescription and are given all the necessary information to begin their treatment journey.



A quick reference tool to facilitate initiation of PrJINARC® for your patients

The JINARC Controlled Hepatic Safety Monitoring and Distribution (HSMD) Programme

Patient name: Patient date of birth:

Patient ID # (Clinic identifier): Current date:

Use this checklist to ensure that your patients have met all the conditions of prescription and have been informed about their treatment prior to initiation.

Initiating your patient on JINARC

About ADPKD	Completed
Review what ADPKD is, what causes it	☐
Discuss symptoms of ADPKD	☐
Answer patient questions about ADPKD	☐
Key steps in the HSMD Programme	**Completed**
Review what JINARC is used for	☐
Advise patient on potential risks and benefits of JINARC	☐
Discuss the need for monthly liver function blood tests	☐
Confirm baseline levels of ALT and AST are <3 times ULN, and ensure total bilirubin and alkaline phosphatase have been assessed	☐
Inform women of childbearing potential that they should have effective contraceptive measures in place prior to and during JINARC use	☐
Provide and review patient information brochure	☐
Introduce the ORIJIN® Patient Support Program (PSP) and discuss its services	☐
Review and co-sign the Patient-Prescriber Agreement Form (PPAF) with patient	☐
Submit the PPAF to the HSMD Programme	☐
Provide patient with monthly liver function test (LFT) (AST and ALT) orders up to the patient's follow-up visit	☐
Taking JINARC	**Completed**
Review dosing, frequency and proper use	☐
Discuss interactions with food/medications	☐
Outline warnings: liver disorder	☐
Outline warnings: pregnancy/breastfeeding/contraception	☐
Discuss side effects and what to do about them	☐
Review emergency situations (dehydration, allergic reactions, etc.)	☐

Consult the JINARC prescriber's guide for more information.

To contact the HSMD Programme team:

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

Fax: 1-844-3JINARC (1-844-354-6272)

The ORIJIN® Patient Support Program

Key support services include:

For patients

- A personal coordinator for **reimbursement/financial assistance**
- Access to **nurses** who provide support **to initiate JINARC** and help answer questions about their treatment
- **Access to the Home Bloodwork Program or phone call reminders** for patients to go for blood tests and to support their treatment journey
- **Pharmacy services** and delivery of JINARC to the patient's home or work

For HCPs

- **Liver function tests** monitoring

For patients and HCPs

- Access to **JINARC.CA**, a website for both **patients** and **HCPs** with a newsletter program exclusive to patients

For more information on ORIJIN, call: 1-844-2JINARC (1-844-254-6272)

PrJINARC® (tolvaptan) is indicated to slow the progression of kidney enlargement and kidney function decline in adult patients with autosomal dominant polycystic kidney disease (ADPKD). In ADPKD, kidney enlargement reflects renal cyst burden.[1]

ALT: alanine aminotransferase; AST: aspartate aminotransferase; ULN: upper limit of normal.

HOW TO INITIATE AND CONTINUE PATIENTS ON PrJINARC®

Follow the prescriber's steps and let ORIJIN® help with the rest!

Prescribers

- Co-sign PPAF with patient
- Provide prescription and LFT orders for HSMD Programme: Every month for 18 months

ORIJIN Team

- Receives, validates and stores PPAF
- Contacts patient to confirm enrollment and understanding of HSMD Programme
- Ships supply of JINARC to pharmacy for dispensing if all PPAF conditions are met
- Sends blood test reminders to patient (as per patient preference)
- Conducts follow-up of LFT result status with prescriber, using the LFT fax-back form

The ORIJIN® Patient Support Program
Experienced, Established and Engaged.

DOSING AND TITRATING [Pr]JINARC®

JINARC: Split-dose regimen

JINARC is taken twice a day. The total daily dose is given as a split-dose regimen, with a higher dose taken in the morning, and a second, lower dose taken 8 hours later.

Dose titration process

Titration intervals should be at least 1 week. Titration should be done judiciously to ensure that high doses are not poorly tolerated through overly-rapid up-titration. In addition, dosing may be down-titrated and up-titrated again as appropriate.

The dose should be up-titrated as shown:

Total daily dose as a split-dose regimen of	**60 mg**	**90 mg**	**120 mg**
	45 mg first thing in the morning	**60 mg** first thing in the morning	**90 mg** first thing in the morning
	15 mg 8 hours later	**30 mg** 8 hours later	**30 mg** 8 hours later

Dose titration goal

The aim of dose titration is to block activity of vasopressin at the renal V_2-receptor as completely and constantly as possible, to achieve optimal effect on TKV progression or diminution of renal function decline while maintaining acceptable fluid balance.

Patients should normally be maintained on the highest tolerated dose.

The importance of adherence

Patients should be told that unnecessary treatment interruption should be avoided, and that daily adherence to JINARC is important to achieve the best possible outcomes in terms of diminution of renal cyst progression and preservation of renal function.

Consult the Product Monograph for full dosing and titration information.

ADMINISTRATION AND MISSED DOSES

[Pr]JINARC® should be taken:

- with or without meals
- without grapefruit juice (and not after eating grapefruit, due to a significant increase in tolvaptan concentrations)

All patients on JINARC should be encouraged to drink water liberally on an ongoing basis in order to match increased urine output, and reduce the likelihood of dehydration and hypernatremia from the aquaretic effects of JINARC. Treatment should be interrupted if the ability to drink or accessibility to water is limited.

Missed doses

If a patient misses a dose, he/she should take the next dose at the scheduled time and prescribed level.

Patients should not take 2 doses at the same time.

DOSAGE ADJUSTMENTS TO [Pr]JINARC®: DRUG-DRUG INTERACTIONS

JINARC is a substrate of CYP3A, and thus co-administration with CYP3A inhibitors or CYP3A inducers may lead to a change in exposure.

Concomitant use with strong CYP3A inducers should be avoided.

Where dose adjustments are recommended or required, response should be monitored, and the dose adjusted accordingly.

Drug category	Adjustments of JINARC
Strong CYP3A inhibitors	Concomitant use with strong CYP3A4 inhibitors is contraindicated as it may lead to significant increase in tolvaptan exposure.
Moderate CYP3A inhibitors	Dose reduction required.
P-gp inhibitors	Dose reduction may be required in patients concomitantly treated with P-gp inhibitors, based on clinical response. However, concomitant use with those P-gp inhibitors that also act as strong CYP3A inhibitors is contraindicated.
CYP3A substrates	In healthy subjects, tolvaptan, a CYP3A substrate, had no effect on the plasma concentrations of some other CYP3A substrates (e.g., warfarin or amiodarone). However, tolvaptan increased plasma levels of lovastatin by 1.3 to 1.4-fold, indicating a potential effect on weak substrates of CYP3A substrates.

DOSAGE ADJUSTMENTS TO OTHER DRUGS, FOODS, AND HERBS

Drug category	Interaction effects
Digoxin	Steady state digoxin concentrations were statistically significantly increased (approximately 30% increase as determined by C_{max} and 20% increase as determined by AUC_t) when digoxin was co-administered with multiple 60 mg doses (QD) of tolvaptan; *in vitro* studies indicate that tolvaptan is a substrate and competitive inhibitor of p-glycoprotein. Patients receiving digoxin should be evaluated for excessive digoxin effects after adding tolvaptan.
Warfarin, amiodarone, furosemide, and hydrochlorothiazide	Co-administration of tolvaptan does not appear to alter the pharmacokinetics of warfarin, furosemide, hydrochlorothiazide, or amiodarone (or its active metabolite, desethylamiodarone) to a clinically significant degree.
Vasopressin analogues	Co-administration not recommended. • In addition to its V_2-receptor mediated renal aquaretic effects, tolvaptan blocks vascular vasopressin V_2-receptors involved in the release of coagulation factors (e.g., von Willebrand's factor) from endothelial cells. Therefore, the effect of vasopressin analogues such as desmopressin may be attenuated in patients using these therapies concomitantly with tolvaptan.

Drug category	Interaction effects
Grapefruit juice	Co-administration of tolvaptan with 240 mL of grapefruit juice produced a doubling of peak tolvaptan concentrations (C_{max}) but had no effect on tolvaptan elimination half-life. ^{Pr}JINARC® should not be taken with grapefruit juice.
St John's Wort	Interactions with herbal products have not been established; however, St John's Wort should be avoided while taking JINARC.
Furosemide or hydro-chlorothiazide (HCTZ): Pharmaco-dynamic interactions	Tolvaptan use alone produces a greater 24-hour urine volume than does furosemide or HCTZ alone. However, concomitant administration of tolvaptan with furosemide or HCTZ results in a 24-hour volume that is similar to that after tolvaptan administration alone. Furosemide co-administered with tolvaptan produces a similar maximal rate of urine excretion compared to furo-semide alone and 70% higher than tolvaptan alone. HCTZ co-administered with tolvaptan produces a slightly higher maximal excretion rate compared to tolvaptan alone and 66% higher compared to HCTZ alone.

Consult the Product Monograph for full dosing and dose adjustment information.

ORIJIN®: THE VALUE-ADDED PATIENT SUPPORT PROGRAM, AVAILABLE FOR PrJINARC® PATIENTS

Key support services include:

For patients

Dedicated Expert Nursing Services

Our expert nurses provide personalized care, treatment education, and emotional support to help your patients manage their PKD journey.

Convenient Home Blood Work Program

We offer convenient home blood work or phone call reminders for liver function monitoring, ensuring easy access and timely results.

No additional cost for branded JINARC

Patients with private insurance have access to a pharmacy Co-Pay card. This is designed to help patients by eliminating any out-of-pocket cost for branded JINARC. This program will cover any potential cost differences between JINARC and the patient's private payer plan.

For patients and HCPs

Dedicated Website

Our website provides current resources, newsletters, and expert tips, along with support from the ORIJIN team to guide patients through their JINARC treatment journey.

Scan here

For over 10 years, [Pr] JINARC® patients and prescribers have had specific access to the various services provided by ORIJIN®, an experienced, established and engaged program designed to support the treatment journey.

For patients

Skilled Reimbursement Assistance

Our reimbursement navigators help patients navigate financial options, enabling informed decisions about accessing JINARC for ADPKD care.

Pharmacy Services and Delivery

Patients have access to a pharmacy team with JINARC expertise and flexible medication delivery to their preferred location, whether at home or work.

Nutritional Support and Educational Webinars

We offer educational webinars led by dietitians specializing in ADPKD, helping patients make informed dietary and lifestyle choices to complement their JINARC treatment.

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

Your direct line to JINARC support

SAFETY INFORMATION

Clinical use:

- In order to select patients who might best benefit from the effects of PrJINARC®, clinical trials evaluated ADPKD patients having a total kidney volume (TKV) ≥750 mL, and/or renal function corresponding to a CKD-EPI eGFR ≥25 mL/min/1.73 m^2, at the time of initiation of treatment.
- JINARC treatment should be initiated and monitored under the supervision of a nephrologist or specialist with expertise in the management of patients with ADPKD and a full understanding of the benefits and risks of tolvaptan therapy including hepatic toxicity and monitoring requirements.
- Careful consideration and discussion of the appropriateness of JINARC treatment should be undertaken between the prescriber and patient before initiation of therapy, taking into account the potential benefits and risks of treatment. Upon mutual agreement to undertake treatment with JINARC, a signed, duly-documented, manufacturer and product-specific patient-prescriber agreement form (PPAF) is required outlining the relevant patient selection criteria to be considered, expected benefits and risks of treatment, and the need for mandatory hepatic function monitoring.
- **JINARC Controlled Hepatic Safety Monitoring and Distribution Programme:** JINARC is available for treatment of patients with ADPKD only through a manufacturer and product-specific controlled hepatic safety monitoring and distribution (HSMD) programme conducted and maintained by, or for, the market authorization holder of JINARC. A duly signed manufacturer and product-specific PPAF is required for enrollment in the HSMD Programme. For more information on the programme, please call 1-844-254-6272.
- Safety and effectiveness have not been established in geriatrics (>65).

Contraindications:

JINARC is contraindicated in:

- Patients who have been asked to permanently discontinue tolvaptan
- Patients with known or suspected hypersensitivity to tolvaptan, benzazepine or benzazepine derivatives (e.g., mirtazapine) or any of the excipients
- Patients with hypovolemia
- Patients with hypernatremia
- Patients with anuria
- Patients who do not have access to fluids or who cannot respond to the physiologic sensation of thirst
- Patients with a history, signs or symptoms of significant liver impairment or injury, excluding uncomplicated polycystic liver disease
- Patients using strong CYP3A inhibitors, e.g., ketoconazole, itraconazole, clarithromycin, telithromycin, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone
- Pregnancy
- Nursing women
- Patients with one of the following rare hereditary diseases: galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption

Most serious warnings and precautions:

Idiosyncratic hepatic toxicity: JINARC use has led to idiosyncratic elevations of blood alanine and aspartate aminotransferases (ALT & AST), rarely associated with concomitant elevations of total bilirubin. To help mitigate the risk of liver injury, blood testing for hepatic transaminases and total bilirubin is required prior to initiation of JINARC, then blood testing for hepatic transaminases is required:

- monthly for 18 months
- every 3 months for the next 12 months
- every 3–6 months thereafter during treatment with JINARC

Therefore, JINARC is available for treatment of patients with ADPKD only through a controlled hepatic safety monitoring and distribution programme conducted and maintained by, or for, the market authorization holder of JINARC.

Other relevant warnings and precautions:

- Risk of dehydration
- Interactions with moderate CYP3A inhibitors, CYP3A inducers or P-glycoprotein inhibitors
- Hepatotoxicity: Acute liver failure
- Anaphylaxis
- Hypernatremia: Concomitant use with hypertonic saline solutions or drugs that may increase serum sodium should be avoided
- Hyperkalemia
- Hyperuricemia
- Hypotension: Co-administration with antihypertensive medications may cause increase in hypotension-related adverse events, including dizziness or syncope
- Serum sodium abnormalities must be corrected prior to JINARC initiation
- Use of contraception in women of childbearing potential
- Vasopressin analogues: Co-administration not recommended
- Caution when driving vehicles or operating machinery

For more information:

Consult the Product Monograph at jinarcmonograph.ca for adverse reactions, interactions, dosing, monitoring tests and conditions of clinical use. The Product Monograph is also available by calling 1-877-341-9245.

References:

1. JINARC Product Monograph. Otsuka Canada Pharmaceutical Inc.
2. Data on file – First Claim. Otsuka Canada Pharmaceutical Inc.
3. Chapman AB, Bost JE, Torres VE *et al. Clin J Am Soc Nephrol* 2012;7:479–86.
4. Grantham JJ, Torres VE, Chapman AB *et al. N Engl J Med* 2006;354:2122–30.

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Pr JINARC® tolvaptan

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