

PART III: CONSUMER INFORMATION**Pr JINARC®
Tolvaptan Tablets**

This leaflet is part III of a three-part "Product Monograph" published when JINARC was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about JINARC. Contact your doctor, nurse or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

JINARC is used in adults to treat autosomal dominant polycystic kidney disease (ADPKD).

ADPKD is a genetic disorder which leads to the growth of multiple cysts (sacs filled with fluid) on the kidneys. Over time, the cysts grow in size, which can damage the way your kidneys work, and may ultimately lead to kidney failure.

JINARC should only be prescribed by a doctor experienced in the diagnosis and treatment of ADPKD.

What it does:

JINARC works by blocking the effects of a hormone called vasopressin, which promotes cyst growth in the kidneys in patients with ADPKD. By blocking the effects of the hormone, JINARC is able to reduce the growth of the cysts in the kidneys and slow the decline of kidney function. This should help protect your kidneys from damage and failure.

Because of the way that JINARC works, you will produce more urine causing you to urinate more frequently during the day and at night. This may become less pronounced over time.

Before starting this medication:

Before taking JINARC you should discuss carefully with your doctor if this medication is suitable for you, taking into consideration the potential benefits and risks involved. Once you and your doctor have agreed that JINARC is suitable for you, your doctor will ask that you sign a patient-prescriber agreement form (PPAF), stating that you understand the benefits and risks of treatment and that you agree to take blood tests as prescribed by your doctor to start and remain on treatment. For more information on JINARC controlled hepatic safety monitoring and distribution programme, please call 1-844-254-6272. 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 on the study, please call 1-877-341-9245 or go to www.clinicaltrials.gov, study ID NCT02925221.

When it should not be used:

Do not take JINARC if:

- you have been asked to permanently discontinue tolvaptan in the past
- you are allergic to tolvaptan, benzazepine or benzazepine derivatives (e.g. REMERON®), or any non-medicinal ingredients in the formulation.
- you can not replace fluids by drinking or you can not 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. The presence of hepatic cysts in and of themselves should not be an impediment to initiation of JINARC treatment.
- you are pregnant or plan to become pregnant. It is not known if JINARC will harm your unborn baby.
- you are breast-feeding. It is not known if JINARC passes into your breast milk. You and your healthcare provider should decide if you will take JINARC or breast-feed. You should not do both.
- your body is not able to make any urine. JINARC will not help your condition.
- you take certain medicines. These medicines could cause you to have too much JINARC in your blood:
 - the antibiotic medicines, clarithromycin or telithromycin
 - the antifungal medicines, ketoconazole or itraconazole
 - the anti-HIV medicines, ritonavir, indinavir, nelfinavir, and saquinavir
 - the antidepressant medicine, nefazodone
- you have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
 because lactose is a non-medicinal ingredient in JINARC.

What the medicinal ingredient is:

tolvaptan

What the non-medicinal ingredients are:

Corn starch, hydroxypropyl cellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, and FD&C Blue No. 2 Aluminum Lake as colorant.

What dosage forms it comes in:

Weekly combination blister packs of 15+15 mg, 30+15 mg, 45+15 mg, 60+30 mg, and 90+30 mg tablets.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions – Liver damage**

Your doctor will arrange blood tests before you start treatment with JINARC and then at regular intervals during treatment to check for changes in your liver function.

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

BEFORE you use JINARC talk to your doctor, nurse or pharmacist if you:

- have difficulty urinating or have an enlarged prostate
- are dehydrated or suffer from excessive vomiting, diarrhea or sweating
- have low levels of sodium in your blood
- have high potassium levels in your blood
- have high levels of uric acid in your blood or gout
- are taking medication to treat high blood pressure
- are less than 18 years old
- have been asked to permanently discontinue tolvaptan in the past

Driving and using machines: Before doing tasks which require special attention, wait until you know how you respond to JINARC. Dizziness, weakness and fainting can occur.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with JINARC: clarithromycin, ketoconazole, ritonavir, saquinavir, rifampicin, phenytoin, carbamazepine, St. John's Wort, cyclosporin, quinidine, verapamil, erythromycin, fluconazole, hypertonic saline solutions, drugs that increase serum sodium concentrations, drugs known to increase serum potassium levels (such as spironolactone), digoxin, consuming grapefruit juice, or vasopressin drugs, such as desmopressin, used to control bleeding.

PROPER USE OF THIS MEDICATION

Always take JINARC exactly as your doctor has prescribed. Check with your doctor, nurse or pharmacist if you are not sure.

You can take JINARC with or without food.

While taking JINARC you will produce more urine, urinate more frequently, and urinate at night. If this causes you concern, consult your doctor, nurse or pharmacist. This side-effect should become less pronounced with time.

To prevent becoming dehydrated, have water available to drink at all times while taking JINARC. Unless your doctor tells you otherwise, drink plenty of water during the day and one or two glasses before going to bed. If you suffer from vomiting, diarrhea or any other condition that might cause you to become dehydrated while taking JINARC call your doctor.

Blood tests:

During treatment with JINARC, your doctor will arrange blood tests to check for changes in your liver function, as follows:

- before starting treatment with JINARC
- every month for the first 18 months, then
- every 3 months thereafter during treatment for the next 12 months, and every 3-6 months thereafter during treatment

Usual adult dose:

- JINARC is to be taken twice a day in two different doses. There are three possible dose combinations that your doctor may prescribe:
 - 45+15 mg, for a total daily dose of 60 mg, or
 - 60+30 mg, for a total daily dose of 90 mg, or
 - 90+30 mg, for a total daily dose of 120 mg.
- Take one tablet of the higher dose (45 mg, 60 mg or 90 mg) in the morning.
- 8 hours later take one tablet of the lower dose (15 mg or 30 mg).
- This schedule was designed to give you the best balance between the amount of medicine in your body and possible side effects (especially night time urination).
- Do not drink grapefruit juice during treatment with JINARC. This could cause you to have too great of a drug effect, while taking JINARC.

Adjusted dose if you are taking certain medicines:

Your doctor will tell you to reduce your usual dose of JINARC if you take certain medicines as these medicines could cause you to have too much JINARC in your blood. Your doctor may reduce your dose to the following:

- o 15 mg + 15 mg, for a total daily dose of 30 mg.
- or
- o 30 mg +15 mg, for a total daily dose of 45 mg.

Overdose: If you think you have taken too much JINARC contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Do not miss or skip doses of JINARC. If you miss a dose, take your next dose at the scheduled time and prescribed level. Do not take 2 doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Thirst
- Increased amount of urine
- Increased frequency of urination during the day and at night
- Headache
- Constipation, diarrhea, dry mouth, indigestion, decreased appetite
- Fatigue, weakness, dizziness
- Trouble sleeping
- Muscle spasms
- Rash, itching
- Abdominal pain

If any of these affects you severely, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Increased levels of potassium in the blood: irregular heart beats, muscle weakness and generally feeling unwell		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Increased levels of uric acid in the blood/Gout: joint pain, commonly in the big toe, followed by redness, swelling, warmth		√	
Uncommon	Dehydration: increased thirst, dry mouth and/or skin, fatigue, decreased amount of urine, headache, dizziness, irregular heart beats			√
Rare or Uncommon	Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Rare or Uncommon	Angioedema and Severe Allergic Reactions: swelling of the face, eyes, or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing, unconsciousness.			√

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.otsukacanada.com

or by contacting the marketer, Otsuka Canada Pharmaceutical Inc., at: 1-877-341-9245.

This leaflet was prepared by Otsuka Pharmaceutical Co., Ltd.

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This is not a complete list of side effects. For any unexpected effects while taking JINARC contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store JINARC between 15°C to 30°C.

Keep JINARC out of sight and reach of children.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mpps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.