JINARC®▼ (tolvaptan):

Important safety information on minimising side effects for patients

This is advice approved by the HPRA

Your doctor has decided to prescribe JINARC for you. You should receive the following items to help you understand your medicine better and to support you during treatment:

- The patient information leaflet (PIL) which is included in the pack with the medicine
- This leaflet on important safety information
- The patient/carer education brochure
- The patient alert card - remember to carry your patient alert card at all times

Read the information given to you carefully and consult your doctor if you have any questions. The key points to note are:

Potential for liver injury

- JINARC may cause your liver not to work properly
- Inform your doctor immediately if you experience some of these symptoms:
  - Tiredness, pain in the abdomen, loss of appetite, dark urine, yellowing of skin or eyes (jaundice), severe dehydration, nausea, vomiting, fever, itching of your skin or flu-like syndrome (joint and muscle pain with fever)
- To check for any changes in your liver function, your doctor will take blood tests before starting treatment with JINARC and every month for the first 18 months of treatment. After 18 months these can be done every three months.

Risk of severe dehydration

- JINARC causes water loss because it increases your urine production
- Drink plenty of fluids, but not grapefruit juice, to avoid excessive thirst or dehydration
- You should drink 1–2 glasses of fluid before bedtime and drink more if you pass urine during the night time
- Special care must be taken if you have a disease that reduces appropriate fluid intake or if you are at an increased risk of water loss e.g. in the case of vomiting or diarrhoea
- Symptoms of dehydration may include increased thirst, dry mouth, feeling tired or sleepy, decreased urination, headache, dry skin and poor skin elasticity, rapid heart rate, dizziness and confusion.

The importance of pregnancy prevention

- Do not take JINARC if you are trying to become pregnant or during pregnancy as it may harm your baby
- If you become pregnant **STOP** your tablets immediately and inform your doctor
- Use at least one effective method of pregnancy prevention
  - For 4 weeks before therapy ➔ during therapy ➔ even in the case of dose interruptions ➔ and for at least another 4 weeks after stopping JINARC
- Do not breastfeed while taking JINARC and for one month after stopping JINARC.

continued overleaf...

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get to HPRA Pharmacovigilance at www.hpra.ie, via Email at medsafety@hpra.ie or via phone: +353 1 676 4971. More information on how to report side effects can be found below.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly to HPRA Pharmacovigilance at www.hpra.ie, via Email at medsafety@hpra.ie or via phone: +353 1 676 4971. By reporting side effects, you can help provide more information on the safety of this medicine. Adverse events can also be reported to Otsuka at opuksafety@otsuka.co.uk or by calling +353 1 695 0725.

For further information, please contact Otsuka Medical Information at medical.information@otsuka-europe.com or call +353 1 695 0725.

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