Otsuka

JINARC® (tolvaptan)

Patient Educational Material

Important safety information on hepatotoxicity/liver injury, dehydration and reproductive risks

This educational material is intended for patients receiving tolvaptan and for carers who support them

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What is the purpose of this material?

This material provides some important information about tolvaptan.

This material will:

- Explain when tolvaptan should not be taken and when you should take extra care whilst taking tolvaptan
- Provide some of the important safety information with respect to the risk that tolvaptan can cause your liver to not work properly, as well as cause excessive water loss and what to do if this occurs

Important: Please read the patient information leaflet found in the medicine packaging, which contains the complete information, including other precautions, you need to know when taking tolvaptan.

Consult your doctor, pharmacist or nurse, if you have any questions about your treatment with tolvaptan.

When not to take tolvaptan?

Your doctor will determine whether it is appropriate for you to receive treatment with tolvaptan. There is potential that tolvaptan can lead to some side effects which may cause your liver not to work properly and can also cause dehydration.

If any of the following apply to you please tell your doctor immediately before taking tolvaptan:

- If you have been told that you have raised levels of liver enzymes in your blood which do not allow treatment with tolvaptan
- If you are unable or unwilling to comply with monthly blood test for checking liver function
- If you have a condition which is associated with a very low blood volume (e.g. severe dehydration or bleeding)
- If you have difficulty realising when you are thirsty or unable to drink sufficient amounts of water
- If you have a condition that increases sodium in your blood
- If you are not passing any urine

You should take extra care while taking tolvaptan and tell your doctor if you have any concerns, for example:

- If you suffer from liver disease, or other medical conditions or illness
- If you cannot drink enough water or if you have to limit your fluid intake or you are at an increased risk of water loss
- If you are not sure that tolvaptan therapy may be appropriate for you

You must also not take tolvaptan if you are you are planning to get pregnant, are pregnant, or breastfeeding or if you are allergic to tolvaptan or any of the other ingredients of this medicine or if you are allergic to benzazepine or benzazepine derivatives (e.g. benazepril, conivaptan, fenoldopam mesylate or mirtazapine).

POSSIBLE SERIOUS SIDE EFFECTS

Liver injury with tolvaptan treatment and the need for regular blood tests

Tolvaptan may cause your liver not to work properly and increase the level of liver enzymes and bilirubin (a substance that can cause yellowing of skin or eyes) in your blood.

You may need to get additional blood testing. Treatment with tolvaptan will be stopped and may be restarted if the blood tests for liver function are normal.

Talk to your doctor before taking tolvaptan if you suffer from liver disease.

To check for any changes in your liver function, your doctor will conduct blood tests:

- Before starting treatment with tolvaptan
- Every month for the first 18 months of treatment
- Every 3 months thereafter

The following signs could indicate that you may have potential liver problems:

- Tiredness
- Loss of appetite
- Pain in the abdomen
- Dark urine
- Yellowing of skin or eyes (jaundice)
- Severe dehydration
- Nausea
- Vomiting
- Itching
- Joint and muscle pain with fever
- Fever

It is important that you contact your doctor if you develop any of the symptoms listed above.

Why is it important to drink plenty of fluids when taking tolvaptan?

Tolvaptan causes water loss because it increases your urine production. This water loss may result in side effects such as dry mouth and thirst or even more severe side effects like kidney problems or severe dehydration.

It is therefore important that you have access to water and that you are able to drink sufficient amounts when you feel thirsty.

Talk to your doctor before taking tolvaptan if you cannot drink enough water or if you have to restrict your fluid intake.

If you have a disease or condition that reduces the amount of fluid you can take in, or if you are at an increased risk of losing water, then you are at an increased risk of becoming dehydrated.

Symptoms of dehydration may include:

- Increased thirst
- Dry mouth
- Feeling tired or sleepy
- Sunken eyes
- Decreased urination
- Dark yellow, strong smelling urine
- Dizziness

It is important that you contact your doctor if you develop any of the symptoms listed above.

Tolvaptan will also make you pass urine more often than before and this may make you more thirsty than usual. You should drink plenty of water or other watery drinks whether or not you feel thirsty in order 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.

If dehydration is left untreated, it can become severe. Severe dehydration is a medical emergency and requires immediate medical attention.

Symptoms can include unusual tiredness, confusion, dizziness, not urinated all day.

If you experience any of these symptoms, contact your doctor / call 111 / go to A&E immediately to seek medical advice.[1]

1. NHS dehydration - available at https://www.nhs.uk/conditions/Dehydration/ (last accessed May 2024).

What is the tolvaptan Patient Card and how should I use it?

When you are first prescribed tolvaptan, you will be given the tolvaptan Patient Card by your doctor or nurse.

This card contains important safety information regarding the risks of liver injury and dehydration while taking tolvaptan and what to do should signs or symptoms occur.

It also contains the emergency contact details of your doctor or treatment centre. The contact details will be added to the card by your healthcare provider.

You should keep it with you in your wallet or bag at all times in case of emergency.

It is important that you show this card to any healthcare professional involved in your medical care.

If you have not received the tolvaptan Patient Card please contact Otsuka at **medical.information@otsuka-europe.com** or call **+44 (0) 203 747 5300**.

Is it safe to take tolvaptan while trying to become pregnant, are pregnant or are breastfeeding?

You must not take tolvaptan if you are trying to become pregnant, are pregnant or are breastfeeding.

This may result in side effects to you and may affect the development of your unborn baby. Women of childbearing potential must use effective and reliable method of pregnancy prevention at least four weeks before therapy is initiated, during therapy and even in the case of dose interruptions, and for at least a further four weeks after stopping tolvaptan.

You must not breastfeed while taking tolvaptan.

In case you become pregnant, stop taking tolvaptan and inform your prescribing doctor immediately so that your pregnancy can be monitored.

Reporting 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.

Please report side effects to the MHRA through the Yellow Card scheme. You can report via: the Yellow Card website **www.mhra.gov.uk/yellowcard**, the free Yellow Card app available from the **Apple App Store** or **Google Play Store**.

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Side effects can also be reported to Otsuka at **opuksafety@otsuka.co.uk** or by calling **0808 168 6726**.

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