REALHEALTH™

Family Ties and Health: Shedding Light on Kidney Disease Across Generations OLD COPY

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This month is Black Family Month, which was first nationally recognized in 2006 to encourage the enrichment of families through education, health, and self-improvement. This observance also encourages families to inspire one another and encourage conversations about health history - especially inherited conditions. This includes diseases like autosomal dominant polycystic kidney disease, or ADPKD, which often gets diagnosed at a later stage in patients of color. Fostering awareness and encouraging early detection within families can work towards bridging the health disparities gap and empower generations with the knowledge and resources needed to combat this hereditary disease.

ADPKD is the most common genetic kidney disorder in the U.S., affecting over 140,000 adults. In fact, each child of a parent with ADPKD has a 50% chance of inheriting the disease. ADPKD is a disease that causes cysts to form on the kidneys. These cysts can make it harder for the kidneys to function, potentially resulting in kidney failure which may require dialysis or a kidney transplant. Alarmingly, kidney failure due to ADPKD occurs earlier in Black and Hispanic patients which is often due to misdiagnosis or delay in diagnosis and treatment.

Risk Factors Among Populations

Conditions that can affect kidney function are more common in people of color, including high blood pressure and diabetes. This factor can mask the symptoms of ADPKD and can be overlooked for Black patients. Another challenge is that people typically do not experience symptoms and signs until they are between the ages of 30 and 50 years old, although they may have been living with the condition for longer.

Moreover, structural barriers may exacerbate health disparities, such as limited access to medical care in underserved communities. For example, for those who are uninsured or living in communities with few medical resources, there is a greater chance of being diagnosed with ADPKD at the end-stage of kidney disease.

Importance of Early Screening and Conversations

With many health conditions, people will typically know that there is something wrong because they don't feel well. However, with ADPKD, damage to the kidneys can take place for years without the person experiencing symptoms. To get a diagnosis, a healthcare provider must screen through ultrasound, MRI, or CT scan. Black patients may be at a higher risk for how quickly ADPKD progresses over time so it's important to work with a nephrologist, a doctor that specializes in kidney care and treatment of kidney diseases, if people think they may have kidney disease or if kidney disease runs in their family. Early detection is key, so it is important for a person with a family history of ADPKD to work with a healthcare team to determine if additional screenings are needed.

An FDA-Approved Treatment to Slow Disease Progression

For adults who are at risk for rapidly progressing ADPKD, JYNARQUE® (tolvaptan) is the only FDA-approved treatment that works to slow the decline of kidney function. In two clinical studies, JYNARQUE® slowed the decline of kidney function across chronic kidney disease (CKD) stages 1 to 4. JYNARQUE® can cause serious liver problems that can lead to the need for a liver transplant or can lead to death. To monitor your liver function, JYNARQUE is only available through the JYNARQUE Risk Evaluation and Mitigation Strategy (REMS) Program. Please see additional Important Safety Information below. For more information, visit www.jynarque.com.

Arm your Family with Health History

Black Family Health Month not only serves as a pivotal moment for communities of color to reflect on their collective well-being but also emphasizes the critical importance of family unity. By doing so, communities can cultivate a culture of openness and transparency, particularly in discussions surrounding health history, to help ensure the long-term health and vitality of these communities. The challenge of ADPKD underscores the critical importance of informed, community-driven approaches to health. By emphasizing early detection, informed care, and family involvement, there is an opportunity to improve the prognosis for individuals with ADPKD or other inherited conditions, and to address the broader health disparities that affect the Black community.

IMPORTANT SAFETY INFORMATION and INDICATION for JYNARQUE® (tolvaptan)

- Serious liver problems. JYNARQUE can cause serious liver problems that can lead to the need for a liver transplant or can lead to death. Stop taking JYNARQUE and call your healthcare provider right away if you get any of the following symptoms:
  - feeling tired
  - loss of appetite
  - nausea

  - right upper stomach (abdomen) pain or tenderness
  - vomiting
  - fever
  - rash
  - itching
  - yellowing of the skin and white part of the eye (jaundice)
  - dark urine

It is important that you have a blood test before you start JYNARQUE to help reduce your risk of liver problems. Your healthcare provider will do a blood test to check your liver:

- before you start taking JYNARQUE
- at 2 weeks and 4 weeks after you start treatment with JYNARQUE
- then monthly for 18 months during treatment with JYNARQUE
- and every 3 months from then on

Because of the risk of serious liver problems, JYNARQUE is only available through a restricted distribution program called the JYNARQUE Risk Evaluation and Mitigation Strategy (REMS) Program.

Do not take JYNARQUE if you:

- have a history of liver problems or have signs or symptoms of liver problems, excluding polycystic liver disease
- cannot feel if you are thirsty or cannot replace fluids by drinking
- have been told that the amount of sodium (salt) in your blood is too high or too low
- are dehydrated
- are allergic to tolvaptan or any of the ingredients in JYNARQUE
- are unable to urinate

Tell your healthcare provider about all your medical conditions, including if you:

- have a history of sodium (salt) levels that are too low
- are pregnant or plan to become pregnant. It is not known if tolvaptan will harm your unborn

baby. Tell your healthcare provider if you become pregnant or think that you may be pregnant

- are breastfeeding or plan to breastfeed. It is not known if tolvaptan passes into your breast milk. Do not breastfeed during your treatment with JYNARQUE. Talk to your healthcare provider about the best way to feed your baby during this time

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

- Taking JYNARQUE with certain medicines could cause you to have too much tolvaptan in your blood. JYNARQUE should not be taken with certain medications. Your healthcare provider can tell you if it is safe to take JYNARQUE with other medicines
- Do not start taking a new medicine without talking to your healthcare provider

JYNARQUE may cause serious side effects, including:

- Too much sodium in your blood (hypernatremia) and loss of too much body fluid (dehydration). In some cases, dehydration can lead to extreme loss of body fluid called hypovolemia. You should drink water when you are thirsty and throughout the day and night. Stop taking JYNARQUE and call your healthcare provider if you cannot drink enough water for any reason, such as not having access to water, or vomiting or diarrhea. Tell your healthcare provider if you get any of the following symptoms:
    - Dizziness
    - Fainting
    - weight loss
    - a change in the way your heart beats
    - feeling confused or weak

What should you avoid while taking JYNARQUE?

Do not drink grapefruit juice during treatment with JYNARQUE. This could cause you to have too much tolvaptan in your blood.

The most common side effects of JYNARQUE are:

- thirst and increased fluid intake

- making large amounts of urine, urinating often, and urinating at night

These are not all the possible side effects of JYNARQUE. Talk to your healthcare provider about any side effect that bothers you or that does not go away. For more information, ask your healthcare provider or pharmacist.

If you have any questions about your health or medicines, talk to your healthcare professional.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

INDICATION:

What is JYNARQUE?

JYNARQUE is a prescription medicine used to slow kidney function decline in adults who are at risk for rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). It is not known if JYNARQUE is safe and effective in children.

Please read FULL PRESCRIBING INFORMATION, including BOXED WARNING, and MEDICATION GUIDE.

References

- McGill, Rita L, Saunders, Milda R, Hayward, Alexandra L, Chapman, Arlene B: Health Disparities in Autosomal Dominant Polycystic Kidney Disease (ADPKD) in the United States. CJASN 17(7):p 976-985, July 2022. | DOI: 10.2215/CJN.00840122
- “What’s behind Racial Disparities in Kidney Disease?” Harvard Health Publishing, 3 Feb. 2021, www.health.harvard.edu/blog/whats-behind-racial-disparities-in-kidney-disease-2021020321842 .
- Willey C, Kamat S, Stellhorn R, Blais J: Analysis of Nationwide Data to Determine the Incidence and Diagnosed Prevalence of Autosomal Dominant Polycystic Kidney Disease in the USA: 2013–2015. Kidney Dis 2019;5:107-117. doi: 10.1159/000494923.
- “What Is ADPKD.” PKD Foundation, 1 Jun. 2021, pkdcure.org/what-is-adpkd/#:~:text=In%20ADPKD%2C%20fluid%2Dfilled%20cysts,kidney%20failure%20by%20age%2050.
- “How is ADPKD Diagnosed.” PKD Foundation, 2022" data-retina9884="https://pkdcure.org/what-is-adpkd/how-is-adpkd-diagnosed.
- “Polycystic Kidney Disease.” Mayo Clinic,

www.mayoclinic.org/diseases-conditions/polycystic-kidney-disease/symptoms-causes/syc-20352820#:~:text=If%20one%20parent%20has%20ADPKD,less%20common%20than%20is%20ADPKD%20.

- Aung TT, Bhandari SK, Chen Q, et al. Autosomal Dominant Polycystic Kidney Disease Prevalence among a Racially Diverse United States Population, 2002 through 2018. Kidney360. 2021;2(12):2010-2015. Published 2021 Sep 22. doi:10.34067/KID.0004522021
- Riley WJ. Health disparities: gaps in access, quality and affordability of medical care. Trans Am Clin Climatol Assoc. 2012;123:167-174.
- Social determinants of health and chronic kidney disease. National Kidney Foundation. October 9, 2023. https://www.kidney.org
- Cleveland Clinic. September 26, 2022. https://my.clevelandclinic.org/health/articles/24214-nephrologist.
- Fukunaga S, Kamei F, Sonoda H, et al. Detection of Autosomal Dominant Polycystic Kidney Disease by Medical Checkup at an Early Stage. Cureus. 2021;13(10):e18595. Published 2021 Oct 8. doi:10.7759/cureus.18595
- “Why Jynarque”. Jynarque, Oct. 2023" data-retina9884="https://www.jynarque.com/why-jynarque.