3 generations of ADPKD.
1 long-awaited treatment.

HOPE is finally here now that treatment is available for people with autosomal dominant polycystic kidney disease (ADPKD).

JYNARQUE is proven to slow kidney function decline in adults who are at risk for rapidly progressing ADPKD.

IMPORTANT SAFETY INFORMATION:
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, fever, loss of appetite, rash, nausea, itching, right upper stomach (abdomen) pain or tenderness, yellowing of the skin and white part of the eye (jaundice), vomiting, dark urine.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
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Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
An important step in managing your ADPKD

The choice to begin treatment with JYNARQUE® (tolvaptan) marks a new step in your journey with ADPKD. With JYNARQUE, you can help slow kidney function decline.

You may have some questions about treating your ADPKD with JYNARQUE and how to manage effects of your new treatment. This brochure will help answer some of those questions.

As always, your doctor should be your main source of information about JYNARQUE. If you have any questions, please talk to your doctor, pharmacist, or another member of your treatment team.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
About ADPKD

ADPKD: a progressive, inherited disease that can affect the whole body

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
What your kidneys do

Your **kidneys** clean your blood to remove waste from your body. Each kidney is made up of about a million little filtering units called **nephrons**. Each nephron has a filter called a **glomerulus**. More than one glomerulus are called glomeruli. As blood passes through the glomeruli, they filter out the waste, which gets taken out of the body through urine.

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For illustration purposes only.

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
How doctors measure kidney function

Doctors use something called GFR, or glomerular filtration rate, to see how well your kidneys are working to filter the blood. GFR can be estimated based on the amount of creatinine—a waste product—you have in your blood. Your doctor can measure your creatinine with a blood test. One unit of GFR is equal to 1 mL/min/1.73m².

The higher your GFR, the better your kidneys are working. Doctors use GFR to decide what stage of chronic kidney disease, or CKD, someone has.

When doctors talk about “disease stages” in ADPKD, they are using these CKD stages. Stage 5, or renal failure, is also called end-stage renal disease, or ESRD.

<table>
<thead>
<tr>
<th>CKD stage</th>
<th>GFR (mL/min/1.73m²)</th>
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<tr>
<td>1</td>
<td>≥90: Normal function</td>
</tr>
<tr>
<td>2</td>
<td>60-89: Mild reduction</td>
</tr>
<tr>
<td>3a</td>
<td>45-59: Mild to moderate reduction</td>
</tr>
<tr>
<td>3b</td>
<td>30-44: Moderate to severe reduction</td>
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<tr>
<td>4</td>
<td>15-29: Severe reduction</td>
</tr>
<tr>
<td>5</td>
<td>&lt;15: Kidney failure</td>
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</table>

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
ADPKD causes cyst growth in the kidneys that gets worse as time goes on

ADPKD is a progressive disease, meaning it gets worse over time. As cysts grow, kidney function continues to get worse, eventually leading to kidney failure. Kidney failure can mean dialysis or transplant. All can lead to continuing health issues.

ADPKD is the leading inherited cause of ESRD. It is also the fourth-leading cause of ESRD overall.

How doctors diagnose ADPKD

Doctors determine if someone has ADPKD based on:

- Family history of the disease
- If the kidneys are bigger than they should be
- The number of cysts in the kidneys
- Other health issues, like high blood pressure

Also, to see how many cysts someone has and how big they are, a doctor might use an ultrasound, computed tomography (CT) scan, or magnetic resonance imaging (MRI).

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
ADPKD is a systemic disease

That means even though it affects the kidneys, it also affects other parts of the body.

These can include:

- blood vessels
- heart
- liver
- pancreas

ADPKD can also cause:

- back or side pain
- kidney stones
- urinary tract infection
- blood in urine

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
ADPKD is an inherited disease

A parent with ADPKD has a 50% chance of passing it on to each child. ADPKD is inherited by male and female children equally.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
Understanding progression

How ADPKD changes over time

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
ADPKD continues to get worse over time

You might notice signs but not know they’re from ADPKD. As your cysts grow, your kidneys can’t always keep up with the body’s demands. Kidney damage builds up. Even if kidney function looks normal. Eventually, the damage is too much, and the kidneys slowly stop working.

Some people with ADPKD feel pain

Pain can be linked to kidney size. Some people feel pain early. But for others, the kidneys might grow for a while before they feel pain. Larger kidneys are linked to infections and burst cysts.

People with fast-progressing ADPKD reach ESRD at a younger age

With rapidly- or fast-progressing ADPKD, kidney function gets worse and cysts grow more quickly, leading to earlier kidney failure. Larger kidneys can lead to earlier high blood pressure, more pain, earlier kidney damage, and early kidney failure.

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
Kidney size is one sign of risk for fast-progressing ADPKD

Doctors measure kidney volume based on height. Then, they see if the kidneys are big for the patient’s age.

For instance, 2 people might have the same size kidneys. But in a shorter person they would be a greater risk. Or, if 2 people of the same height have the same size kidneys, the younger person may be at risk for faster progressing ADPKD.

**PATIENT 1**
35 years old
Height: 6'5"
May not be at risk for fast-progressing ADPKD

**PATIENT 2**
35 years old
Height: 5'9"
May be at risk for fast-progressing ADPKD

**PATIENT 3**
65 years old
Height: 5'9"
May not be at risk for fast-progressing ADPKD

Each of these patients has a combined kidney volume of 800 mL. Each of their kidneys is about 400 mL, which is slightly more than 13 fluid oz.

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
What are some other signs of risk for fast-progressing ADPKD?

Other signs include:
• High blood pressure before age 35
• Blood in the urine before age 35
• Kidney failure before the age of 58 in one's family
• A fast drop in GFR
• Being male
• Certain types of inherited genetic mutations

Continuing to work with a doctor can help a patient learn more about how his or her kidneys look and how fast the disease is progressing. This could include a doctor using an MRI to get a more detailed picture of the kidneys.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
What JYNARQUE® (tolvaptan) does

JYNARQUE is proven to slow kidney function decline in adults who are at risk for rapidly progressing ADPKD.

SELECT IMPORTANT SAFETY INFORMATION:

- **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

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
JYNARQUE® (tolvaptan) slows the decline in kidney function

*Kidney function was measured by estimated glomerular filtration rate (eGFR).

In a clinical trial of ADPKD patients with CKD stages 2-4, kidney function, or eGFR, was 1.3 higher on average for people taking JYNARQUE than for people taking placebo at the end of the 1-year study. *

*SELECT IMPORTANT SAFETY INFORMATION:*

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.

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
In a clinical trial of ADPKD patients with CKD stages 1-3, patients taking JYNARQUE had greater kidney function (eGFR was 3.26 higher) than the patients who were taking placebo at the end of the 3-year study.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
Patients taking JYNARQUE® (tolvaptan) had less kidney pain

In a clinical trial of ADPKD patients with CKD stages 1-3,

patients taking JYNARQUE had

36%

FEWER PAIN EVENTS
requiring medication or other treatment than those taking placebo

SELECT IMPORTANT SAFETY INFORMATION:
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

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
JYNARQUE® (tolvaptan) works at different stages of disease

JYNARQUE is appropriate for adults with ADPKD at stages 1-4 of CKD who are at risk for rapidly progressing disease. Whether your GFR is 90 or 30, JYNARQUE may help.

JYNARQUE may change the course of your disease by slowing kidney function decline as it works over a period of years

As you take JYNARQUE, remember that it is a long-term treatment and can take time to make a difference.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
How JYNARQUE® (tolvaptan) works

JYNARQUE works by blocking vasopressin

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
For people with ADPKD, JYNARQUE® (tolvaptan) targets the mechanisms that may lead cysts to grow.

This is vasopressin. It is a hormone that maintains the volume of water in the fluid space surrounding cells.

This is necessary for proper cell function.

People with ADPKD have too much vasopressin, which causes cyst growth.

JYNARQUE works by blocking vasopressin. This makes it harder for cysts to grow.

SELECT IMPORTANT SAFETY INFORMATION:
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

For illustration purposes only.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
05

JYNARQUE® (tolvaptan)
REMS Safety Program

Your doctor will need to monitor your liver health while you are taking JYNARQUE

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
JYNARQUE can cause serious and potentially fatal liver injury.

The JYNARQUE Risk Evaluation and Mitigation Strategy (REMS) Program was set up to help reduce this risk for people taking JYNARQUE.

- In clinical trials, about 5% of people taking JYNARQUE and 1% of people taking placebo experienced signs of liver injuries

  - In time, after JYNARQUE was stopped, there was no longer any sign of liver injury

SELECT IMPORTANT SAFETY INFORMATION:
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

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
To reduce your risk of liver injury while taking JYNARQUE® (tolvaptan), it is required that you have a blood test before you start JYNARQUE, then 2 weeks and 4 weeks after you start.

- After that, for the first 18 months of treatment with JYNARQUE, you will need to have a blood test every month.
- When that is done, you will only need to do a blood test every 3 months to be able to continue on JYNARQUE.

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

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
06

Serious side effects

JYNARQUE® (tolvaptan) may cause serious side effects

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
Serious side effects may include:

- **Liver injuries.** Learn more about liver injuries and the JYNARQUE REMS Safety Program on pages 21-23

- **Too much sodium in your blood (hyponatremia) 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

Call your healthcare provider right away if you have any of the above symptoms.

JYNARQUE has been studied in over 3000 patients with ADPKD.

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
Common side effects

Most common side effects to be ready for

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
The most common side effects may take some lifestyle adjustments

JYNARQUE may cause side effects, including excessive thirst and urination. These side effects are related to how JYNARQUE works in the kidneys.

Why do these side effects happen?

Vasopressin works differently in normal kidney cells. There, it helps control the amount of water in your body. When vasopressin is blocked by JYNARQUE, your body holds on to less water, which could make you thirstier and give you the urge to urinate more.

SELECT IMPORTANT SAFETY INFORMATION:

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

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
Being ready for the most common side effects of JYNARQUE® (tolvaptan)

In clinical studies, just under 2 in 3 people (64%) felt thirsty while taking JYNARQUE.

In clinical studies, just under 3 in 4 people (70%) had increased urination, including needing to wake up from sleep to urinate, urinating greater amounts, and urinating more often during the day.

**PRACTICAL STEP:**
Try taking a water bottle with you everywhere so you always have something to drink.

**PRACTICAL STEP:**
Wherever you go, plan ahead by finding out where the restrooms are.

**PRACTICAL STEP:**
Take your first JYNARQUE dose upon waking and the second dose exactly 8 hours later and you may be able to reduce the need to wake up to urinate.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
In clinical studies, Most people adjusted to taking JYNARQUE® (tolvaptan) and were able to continue treatment

For people who took JYNARQUE in clinical trials, the first 2 to 4 months were critical to adjusting to side effects like thirst, frequent urination, and waking up to urinate. Most people who made it past the early period with JYNARQUE stayed with it for the duration

- In a clinical study of patients with CKD stages 2-4, after the first 5 weeks, these side effects were reported less often

In a clinical study of patients with CKD stages 1-3, nearly all patients who took JYNARQUE were able to keep taking it every day

- 88% of people taking JYNARQUE were able to do so every day 90% of the time
- 75% of patients who made it to 3 years with JYNARQUE said they could keep taking their current dose for as long as their doctor tells them to

If you are younger, or early in your disease, these side effects might be worse.

If you are early in your disease and have trouble tolerating JYNARQUE, you can stop taking it. At a later date, if you and your doctor agree it is right for you, you can start taking JYNARQUE again.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.

SELECT IMPORTANT SAFETY INFORMATION:
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
08

Resources for you

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
Lifestyle tips

Taking JYNARQUE may change the course of your disease. But it will likely mean some lifestyle changes. These are some tips that might help you get adjusted:

Speak up

• Talk to your doctor to make sure you know exactly how to take JYNARQUE
• Tell your whole healthcare team, including your healthcare providers and pharmacists, that you are taking JYNARQUE
• If you feel comfortable, you may want to talk to people you know about your treatment, including the need for water and frequent bathroom visits

Keep to a schedule

• Set a recurring event in your calendar to remind you when lab testing and other appointments are scheduled
• Set alarms on your phone to help remind you when to take JYNARQUE

Make a plan

• Download an app you can use to find nearby restrooms while traveling
• Have some extra water containers handy—in the office, at home, and in the car
• Make sure to urinate before meetings, dinner time, movies, or other social events

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.

SELECT IMPORTANT SAFETY INFORMATION:
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.
How to take JYNARQUE® (tolvaptan)

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
You and your doctor will work to find the JYNARQUE® (tolvaptan) dose that is right for you

Take JYNARQUE twice a day, unless advised otherwise by your doctor

- The starting dose for JYNARQUE is 60 mg/day
- Your doctor might increase your dose of JYNARQUE to make sure it's doing the most it can
- It is important to take both JYNARQUE doses prescribed to make sure it is working all day long

- JYNARQUE may be taken with or without meals
- Do not drink grapefruit juice during treatment with JYNARQUE. This could cause you to have too much JYNARQUE in your blood
- If you miss a dose of JYNARQUE, do not double up. Take the next dose when you normally would

JYNARQUE comes in weekly blister packs, labeled with the days of the week. The morning and afternoon doses are clearly labeled “AM” and “PM”

- Take the first dose upon waking; take the second dose 8 hours later. Taking your second dose 8 hours after the first can help reduce the need to wake up to urinate

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.

SELECT IMPORTANT SAFETY INFORMATION:
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
10

Dosages

You and your doctor will work to find the JYNARQUE® (tolvaptan) dose that is right for you.

Please read **IMPORTANT SAFETY INFORMATION** on pages 38-39.
JYNARQUE® (tolvaptan) comes in 5 dose strengths*

- 15-mg tablet (Triangular)
- 30-mg tablet (Round)
- 45-mg tablet (Square)
- 60-mg tablet (Rectangular)
- 90-mg tablet (Pentagonal)

JYNARQUE comes in 3 dose combinations

- 120 mg: 90/30 mg
- 90 mg: 60/30 mg
- 60 mg: 45/15 mg

SELECT IMPORTANT SAFETY INFORMATION:
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.

*Not actual size. Not all dose strengths are packaged together.

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
Talking to your family about JYNARQUE® (tolvaptan)

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
ADPKD is an inherited disease. You may want to talk about JYNARQUE® (tolvaptan) with your family members

- If you are comfortable talking to your family members about your ADPKD treatment plan, this information might help them understand what you’re going through
- Sharing your experiences with JYNARQUE may help your family members learn about the medication you’re on
- Since ADPKD is an inherited disease, there might be other people in your family who have it. It might also help them to know the options available to adults living with ADPKD

Please read IMPORTANT SAFETY INFORMATION on pages 38-39.
INDICATION and IMPORTANT SAFETY INFORMATION for JYNARQUE® (tolvaptan)

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.

IMPORTANT SAFETY INFORMATION:

• **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

(continued on next page)
IMPORTANT SAFETY INFORMATION (cont’d)

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).

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