



For caregivers of children with classic CAH

## Get to Know CRENESSITY

The first-ever FDA-approved treatment developed just for people with classic CAH



### Approved Uses:

CRENESSITY (crinecerfont) is a prescription medicine used together with glucocorticoids (steroids) to control androgen (testosterone-like hormone) levels in adults and children 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

### SELECT IMPORTANT SAFETY INFORMATION

**Do not take CRENESSITY if you:** Are allergic to crinecerfont, or any of the ingredients in CRENESSITY.

Please see additional Important Safety Information on page 16 and [Patient Information](#).

# Expect more from classic CAH treatment with CRENESSITY



## Lower steroid doses

CRENESSITY is the only FDA-approved treatment that enables people with classic CAH to reduce their daily dose of steroids.



## Improved androgen control

CRENESSITY lowers ACTH and androgen levels, both of which can be elevated in people with CAH.



## Twice-daily dosing

Steady levels of CRENESSITY around the clock help ACTH and androgen levels stay more consistent throughout the day.



## Demonstrated safety profile

Headache, stomach pain, tiredness, nasal congestion, and nosebleeds were the most common side effects in children taking CRENESSITY. Most side effects were temporary and mild to moderate in severity.



## Studied in a range of people with CAH

The clinical study program was the largest, most extensive exploration of a treatment for classic CAH and included a diverse group of children, teens, and adults aged 4 years and older.



## One-on-one, personalized support

Neurocrine Access Support is a free comprehensive program to help you fill your child's prescriptions, answer your questions, and find financial options to help pay for CRENESSITY.

ACTH=adrenocorticotropic hormone.

## SELECT IMPORTANT SAFETY INFORMATION

**CRENESSITY may cause serious side effects, including:**

**Allergic reactions.** Symptoms of an allergic reaction include tightness of the throat, trouble breathing or swallowing, swelling of the lips, tongue, or face, and rash. If you have an allergic reaction to CRENESSITY, get emergency medical help right away and stop taking CRENESSITY.

**Please see additional Important Safety Information on page 16 and Patient Information.**



# CRENESSITY is for people aged 4 and older with classic CAH

Developed to improve androgen levels, enabling lower steroid doses

## Sophia | 6-year-old with CAH and her father, Michael

- Sophia's father is concerned about the effects of excess androgens on her growth
- Michael would prefer not to have to wake up Sophia in the middle of the night for a steroid dose but feels it's currently necessary to control her androgen levels
- Steroid: hydrocortisone
  - Dose: 4x/day (daily total, 15 mg)
- Androstenedione: elevated (70 ng/dL)



## Kyle | 10-year-old with CAH and his mother, Jessica

- Kyle's mother is worried that symptoms of excess androgens, such as early puberty, acne, and excess hair, will make him feel different from his peers
- Steroid: hydrocortisone
  - Dose: 3x/day (daily total, 20 mg)
- Androstenedione: elevated (150 ng/dL)



Stories and photos are for illustration only and do not represent real patients.

## What is ACTH?

ACTH is a hormone your body makes that signals the adrenal glands to produce cortisol and androgens. Because the adrenal glands can't produce cortisol in people with CAH, the ACTH signal triggers excess androgen production instead.

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**Risk of Sudden Adrenal Insufficiency or Adrenal Crisis with Too Little Glucocorticoid (Steroid) Medicine.** Sudden adrenal insufficiency or adrenal crisis can happen in people with congenital adrenal hyperplasia who are not taking enough glucocorticoid (steroid) medicine. You should continue taking your glucocorticoid (steroid) medicine during treatment with CRENESSITY. Certain conditions such as infection, severe injury, or shock may increase your risk for sudden adrenal insufficiency or adrenal crisis. Tell your healthcare provider if you get a severe injury, infection, illness, or have planned surgery during treatment. Your healthcare provider may need to change your dose of glucocorticoid (steroid) medicine.

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## Laila | 16-year-old with CAH

- Currently unhappy with weight gain due to high-dose steroids. She and her mom are anxious about the long-term risks associated with high-dose steroids that they've talked about with her doctor
- Would prefer to take lower steroid doses but concerned about facial hair growth and irregular periods if her androgen levels rise
- Steroid: prednisone
  - Dose: 2×/day (daily total, 7 mg)
- Androstenedione: within target range (250 ng/dL)



## Patrick | 38-year-old with CAH

- Struggling to manage his weight and is pre-diabetic. Worries that lifelong high-dose steroid use is leading to full-blown diabetes
- Steroid: dexamethasone
  - Dose: 1×/day (daily total, 0.5 mg)
- Androstenedione: within target range (185 ng/dL)



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## What is androstenedione?

Androstenedione is an androgen. It's often measured in bloodwork, along with 17-OHP, to evaluate ACTH and androgen levels in people with CAH. Androstenedione levels vary based on a number of factors.

**Talk to your child's doctor about what is an appropriate level for your child based on their age, gender, and other factors.**

17-OHP=17-hydroxyprogesterone.

## SELECT IMPORTANT SAFETY INFORMATION

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

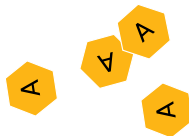
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# Managing CAH with steroids alone is challenging

You may know that too little **cortisol** can result in nausea, dizziness, and even adrenal crisis.

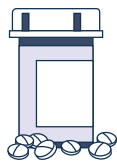
For people with CAH, low cortisol can also cause too many **androgens**. When the adrenal glands can't make cortisol, they end up making the hormone they *can* make—**androgens**. So a byproduct of not being able to make cortisol is too many androgens.



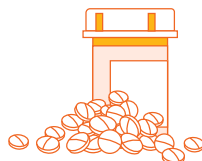
## What are androgens?

Androgens such as testosterone are hormones that help regulate growth and reproduction. Having too many can cause symptoms like early puberty and fertility issues.

## Treating CAH with steroids alone is often a compromise between competing health risks.



**Steroids, in lower doses**, can be used effectively to **replace cortisol** but often are not enough to treat excess androgens.



**Higher steroid doses** can be used to manage excess **androgens**; however, those high doses carry additional health risks.

## SELECT IMPORTANT SAFETY INFORMATION

**The most common side effects of CRENESSITY in adults include** tiredness, headache, dizziness, joint pain, back pain, decreased appetite, and muscle pain.

**The most common side effects of CRENESSITY in children include** headache, stomach pain, tiredness, nasal congestion, and nosebleeds.

These are not all the possible side effects of CRENESSITY. Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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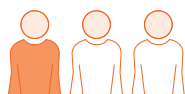
# Treatment with high-dose steroids alone can come at a cost

Steroid doses given for CAH typically cannot do both: effectively reduce excess androgens and avoid health risks of high-dose steroids. This creates a tug-of-war between the opposing options.

Symptoms of excess ACTH/androgens may include:	Risks of high-dose steroids may include:
<ul style="list-style-type: none"><li>• Early puberty</li><li>• Short stature</li><li>• Irregular periods</li><li>• Infertility</li><li>• Acne</li><li>• Excessive hair growth</li><li>• Mental health issues</li><li>• Testicular and ovarian adrenal rest tumors (TARTs and OARTs)</li></ul>	<ul style="list-style-type: none"><li>• Obesity</li><li>• Diabetes</li><li>• Low bone density (osteoporosis)</li><li>• Anxiety</li><li>• Depression</li><li>• Memory issues</li><li>• High cholesterol</li><li>• High blood pressure</li><li>• Heart disease</li></ul>



Based on two studies, **2 out of 3 people with CAH** have poorly managed androgen levels.



A separate study found that **1 out of 3 young adults with CAH** is already being treated for conditions associated with taking high-dose steroids.



It's time to rethink how to manage the tradeoffs between excess androgens and high-dose steroids. Consider what may be possible by changing your child's CAH treatment plan.

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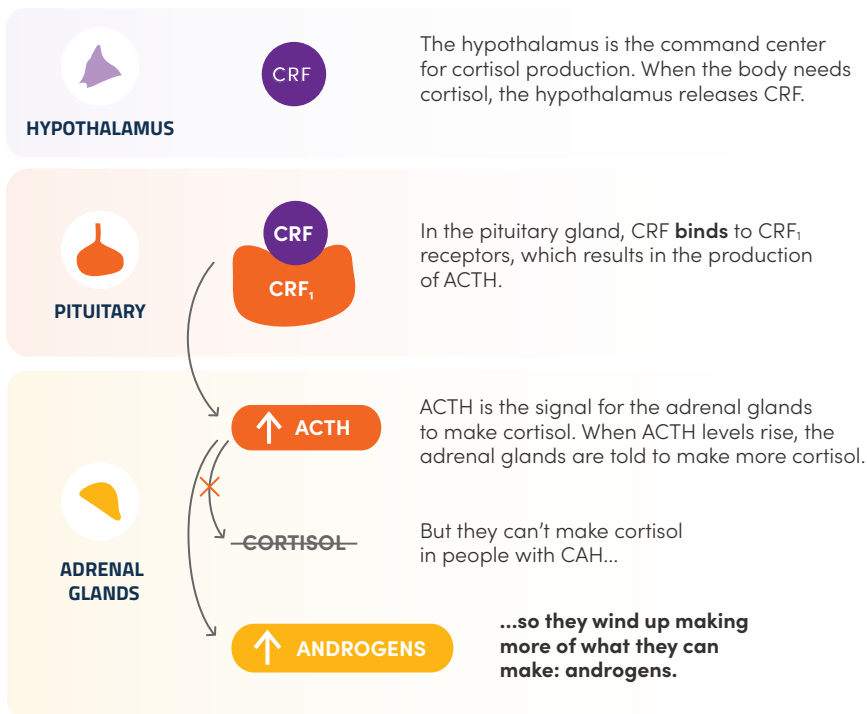
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# Treatment with CRENESSITY is a cutting-edge way to manage androgens

## How CAH affects androgen production

In people with CAH, lack of cortisol leads the hypothalamus to continuously release CRF, which results in excessive production of ACTH and androgens. Here's how:



CRF=corticotropin-releasing factor; CRF<sub>1</sub>=corticotropin-releasing factor type 1.



**Has your child's doctor talked about using steroids for "suppression"? High-dose steroids tell the hypothalamus to release less CRF, which results in some suppression of ACTH overproduction.**

See additional information on the next page.

## SELECT IMPORTANT SAFETY INFORMATION

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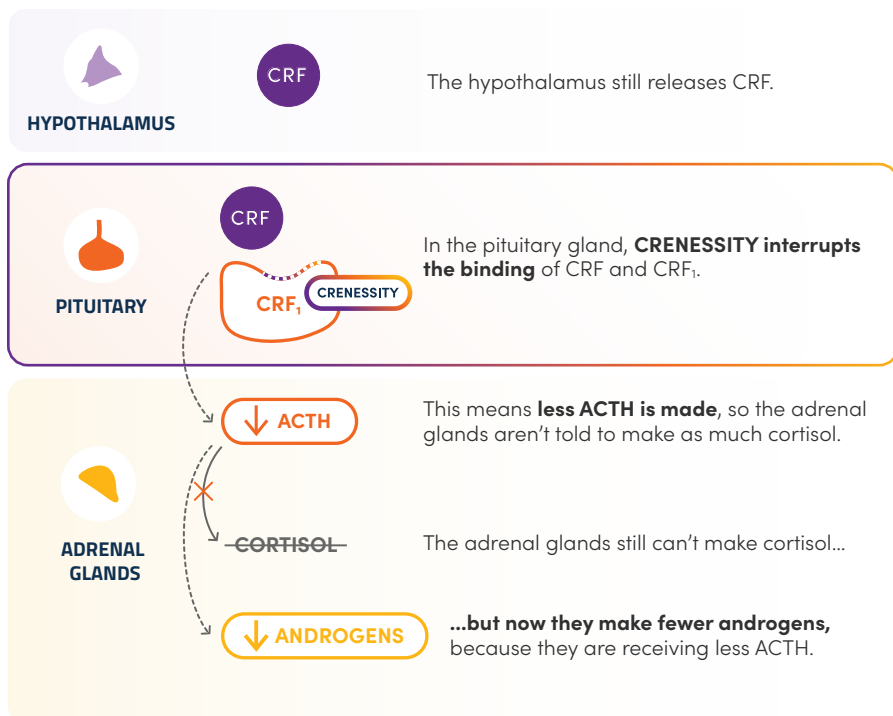
**Allergic reactions.** Symptoms of an allergic reaction include tightness of the throat, trouble breathing or swallowing, swelling of the lips, tongue, or face, and rash. If you have an allergic reaction to CRENESSITY, get emergency medical help right away and stop taking CRENESSITY.

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## How CRENESSITY works to reduce androgens

CRENESSITY is believed to target a key connection in the process of making androgens.



**CRENESSITY directly interrupts the path that overproduces ACTH and androgens.**

That means you can now use:

- CRENESSITY to manage androgens
- Steroids in lower amounts, primarily to replace cortisol

### SELECT IMPORTANT SAFETY INFORMATION

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**Risk of Sudden Adrenal Insufficiency or Adrenal Crisis with Too Little Glucocorticoid (Steroid) Medicine.** Sudden adrenal insufficiency or adrenal crisis can happen in

people with congenital adrenal hyperplasia who are not taking enough glucocorticoid (steroid) medicine. You should continue taking your glucocorticoid (steroid) medicine during treatment with CRENESSITY. Certain conditions such as infection, severe injury, or shock may increase your risk for sudden adrenal insufficiency or adrenal crisis. Tell your healthcare provider if you get a severe injury, infection, illness, or have planned surgery during treatment. Your healthcare provider may need to change your dose of glucocorticoid (steroid) medicine.

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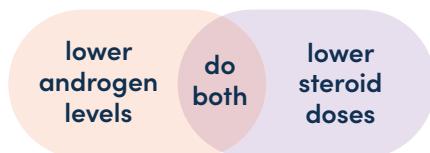




# Tested in the largest clinical study program for a classic CAH treatment

## The program included two studies: one in children and one in adults.

Both CRENESSITY studies were designed to address the priorities of people with CAH. They tested whether CRENESSITY could:



Read about the study in children below and go to [CRENESSITY.com/adults](https://crenessity.com/adults) to learn about the study in adults.

## The study in children included 103 participants aged 4 to 17 years with classic CAH.

At the start of the study, all participants had to be taking a steroid dose greater than the range needed to replace cortisol.



69 took CRENESSITY



34 took placebo



Throughout the study, both groups took enough steroid medication to ensure they were within or above the range needed to replace cortisol.

The period of the study in which CRENESSITY was compared with placebo (the placebo period) lasted 28 weeks.

### What is placebo?

Placebo is a substance that has no effect on the body. Clinical studies are often designed to compare the effects of a medicine with those of placebo to see if the medicine met its goals.

## SELECT IMPORTANT SAFETY INFORMATION

**CRENESSITY may cause serious side effects, including:**

**Risk of Sudden Adrenal Insufficiency or Adrenal Crisis with Too Little**

**Glucocorticoid (Steroid) Medicine.** Sudden adrenal insufficiency or adrenal crisis can happen in people with congenital adrenal hyperplasia who are not taking enough glucocorticoid (steroid) medicine. You should continue taking your glucocorticoid (steroid) medicine during treatment with CRENESSITY.

**(continued on the next page)**

Please see additional Important Safety Information on page 16 and [Patient Information](#).



# In the study, lowering androgen levels with CRENESSITY enabled reduced steroid doses

## Androgen levels improved substantially



~4x

**greater androstenedione improvement** in children taking CRENESSITY compared with those taking placebo\*

~12x

**greater 17-OHP improvement** in children taking CRENESSITY compared with those taking placebo†

## Steroid doses were lowered significantly



~4x

**greater steroid dose reduction** in children taking CRENESSITY compared with those taking placebo‡

Steroid doses were adjusted under careful supervision of doctors. No children taking CRENESSITY experienced adrenal crisis.

CRENESSITY does not address cortisol deficiency. Children taking CRENESSITY should continue taking steroids to replace missing cortisol.

\*Androstenedione levels were reduced by 197 ng/dL in children taking CRENESSITY compared with an increase of 71 ng/dL with placebo.

†17-OHP levels were reduced by 5865 ng/dL in children taking CRENESSITY compared with an increase of 556 ng/dL with placebo.

‡Children treated with CRENESSITY were able to reduce their steroid dose by 18% compared with an increase of 6% with placebo.

**After the placebo period of the study ended, 97 of the 103 children (94%) chose to continue in the study, with all participants taking CRENESSITY.**



**Ask your child's doctor how CRENESSITY can help your child start a new chapter in CAH management.**

## SELECT IMPORTANT SAFETY INFORMATION

**Risk of Sudden Adrenal Insufficiency or Adrenal Crisis with Too Little Glucocorticoid (Steroid) Medicine (continued).** Certain conditions such as infection, severe injury, or shock may increase your risk for sudden adrenal insufficiency or adrenal crisis. Tell your healthcare provider if you get a severe injury, infection, illness, or have planned surgery during treatment. Your healthcare provider may need to change your dose of glucocorticoid (steroid) medicine.

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# CRENESSITY has a demonstrated safety profile in children



**Headache, stomach pain, tiredness, nasal congestion, and nosebleeds** were the most common side effects in children taking CRENESSITY.



Most side effects were **temporary** and **mild to moderate** in severity.\*



**100% of children taking CRENESSITY** completed the ~7-month (28-week) study.



**Adrenal insufficiency and crisis are risks of living with CAH that CRENESSITY does not address and can occur when your child's steroid dose is too low.**

**In the CAHtalyst™ Pediatric clinical study, no patients experienced adrenal crisis.**

**Please talk to your child's doctor about how to manage their steroid dosing while taking CRENESSITY.**

Acute adrenal crisis can occur in patients with underlying adrenal insufficiency, especially in situations associated with increased cortisol need, such as acute illness, serious trauma, or surgical procedures.

\*A total of 3% of patients treated with CRENESSITY and no placebo-treated patients discontinued treatment because of adverse reactions of abdominal pain, myalgia, and dizziness.

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

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# Take it twice daily for steady androgen levels around the clock

## Taking CRENESSITY



CRENESSITY comes in a capsule or as an oral solution (liquid). Take CRENESSITY twice daily by mouth with morning and evening meals.



Ask your child's doctor if it's possible to time their steroid doses with their CRENESSITY doses.



In case of a missed dose, take another dose as soon as possible, even if that means taking 2 doses close together. Then resume their regular dosing schedule.

- Your child should take CRENESSITY exactly as their doctor tells them to
- Talk to your child's doctor before stopping CRENESSITY
- Do not stop or change your child's steroid dosing unless their doctor says to

## In children, dosing is based on weight:

Weight	Recommended Dosage Regimen
22 lb to <44 lb (10 to <20 kg)	25 mg twice daily (50 mg each day)
44 lb to <121 lb (20 to <55 kg)	50 mg twice daily (100 mg each day)
≥121 lb (≥55 kg)	100 mg twice daily (200 mg each day)



Confirm your child's next appointment with their doctor and have your questions answered about CRENESSITY.

## SELECT IMPORTANT SAFETY INFORMATION

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# Discuss changes to your child's steroid regimen with their doctor

## Because CRENESSITY lowers androgens, your child's doctor may reduce their steroid dose.

- CRENESSITY does not treat cortisol insufficiency, so steroids are still needed
- Talk to your child's doctor about a plan to reduce their steroid dose over time and make sure to continue stress dosing when they need it
- Your child's lab values and clinical symptoms will help your child's doctor guide steroid dose reduction
- Talk to your child's doctor about what to expect and how your child feels as their body adjusts to a lower steroid dose

### Sophia and Michael's Story

#### 6-year-old with CAH and her father, Michael

- Sophia has been taking CRENESSITY for 9 months
- Over the last few months, Sophia's doctor lowered her hydrocortisone dose by 2.5 mg/day to a total of 12.5 mg/day, and they are discussing potential changes to the number of doses per day
- Androstenedione levels were elevated when Sophia started CRENESSITY but are now in a range her doctor thinks is right for her
- Michael is glad his daughter is using lower doses of steroids and that her androgens are controlled



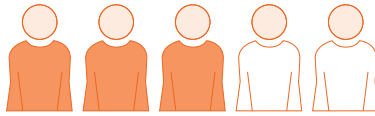
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## The majority of children taking CRENESSITY were able to lower their steroid doses.



Almost 3 of 5 children taking CRENESSITY in the study were able to lower their steroid dose by 2.5 mg/m<sup>2</sup>/day or to the cortisol replacement range while maintaining or improving androgen levels from when they started in the study.\*

\*Almost 3 of 5 represents 38 of 67 children taking CRENESSITY. A total of 3% (1 of 31) children taking placebo achieved this same endpoint. In a separate analysis, 30% (20/67) of children taking CRENESSITY achieved cortisol replacement doses, but no children (0/31) taking placebo were able to.



Ask your child's doctor about reevaluating your child's steroid dosing schedule after starting on CRENESSITY.

### Laila's Story

#### | 16-year-old with CAH

- Has been taking CRENESSITY for a little over a year
- After she was on CRENESSITY for a few months, her doctor gradually lowered her prednisone dose from 7 to 5 mg/day, a total reduction of 2 mg/day
- Her androstenedione levels have remained in a range her doctor thinks is right for her
- Laila is pleased that her androgen levels remained stable after she lowered her steroid dose, and she and her doctor are optimistic about this new treatment regimen



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## NEUROCRINE ACCESS SUPPORT

# Dedicated support available for your child's journey with CRENESSITY

### Your Care Coordinator



Once your child is prescribed CRENESSITY, you will have a dedicated Care Coordinator who is just a phone call away to provide help and guidance. Your Care Coordinator will walk you through the support program offerings and verify your insurance details to begin navigating access to your child's medicine. Please expect a phone call from 1-855-CRNSITY (276-7489) and click [here](#) to save this number for ongoing support.

### You and your specialty pharmacy



As part of our personalized care plan for you, we've partnered with a specialty pharmacy, PANTHERx, to dispense CRENESSITY. Unlike other pharmacies, specialty pharmacies focus on specific, often rare conditions and the medication required to treat them. A CAH-trained pharmacist is available to you at any time, day or night, to support your questions and needs.

### Financial support options



If there is a delay in starting treatment due to insurance coverage, our QuickStart Program offers a free 30-day supply of CRENESSITY.\*

Most patients may pay \$10 or less per month for CRENESSITY.\*

Our Patient Assistance Program may provide CRENESSITY for free if you don't have insurance, your insurance doesn't cover CRENESSITY, or you lack the financial resources to pay for your child's prescription.



Neurocrine Access Support is more than just help with your child's medication. It's a comprehensive program designed to ensure you have everything you need for your child to begin and continue taking CRENESSITY.

\*Additional terms & conditions apply.

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**Dosage Forms and Strengths:** CRENESSITY is available in 50 mg and 100 mg capsules, and as an oral solution of 50 mg/mL.

Please see full [Prescribing Information](#).



# Manage CAH like never before



**CRENESSITY offers a groundbreaking approach to androgen suppression, which allows people with classic CAH to take lower doses of steroids.**

## Lower steroid doses

CRENESSITY allowed people with classic CAH to reduce their daily dose of steroids.\*



## Improved androgen management

CRENESSITY reduces androgen levels.



## Demonstrated safety profile

CRENESSITY has an established safety profile in clinical studies. The most common side effects in children taking CRENESSITY were headache, stomach pain, tiredness, nasal congestion, and nosebleeds.



## Dedicated support

Neurocrine Access Support for CRENESSITY is here to help you every step of the way.

Visit [NBlaccess.com/cft-pt](https://NBlaccess.com/cft-pt) for more information.

**1-855-CRNSITY**  
**(276-7489)**

\*CRENESSITY does not address cortisol deficiency. People taking CRENESSITY should continue taking steroids to replace missing cortisol.

**Visit our website to learn more about CRENESSITY's innovative approach to CAH management and sign up for updates.**

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