



For adults 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

Tiredness, headache, dizziness, joint pain, back pain, decreased appetite, and muscle pain were the most common side effects in adults 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 prescriptions, answer your questions, and find financial options to help pay for CRENESSITY.

ACTH=adrenocorticotrophic 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**

## Emily | 9-year-old with CAH and her mother, Dawn

- Emily's mother worries that early puberty and excess hair due to high androgen levels will make Emily feel different from her peers
- Steroid: hydrocortisone
  - Dose: 3×/day (daily total, 17.5 mg)
- Androstenedione: elevated (150 ng/dL)



## Stephen | 19-year-old with CAH

- Feels self-conscious about his acne and worries about the risk of TARTs if his ACTH and androgens are not well controlled
- Steroid: prednisone
  - Dose: 2×/day (daily total, 7 mg)
- Androstenedione: elevated (350 ng/dL)



TARTs=testicular adrenal rest tumors.

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.

## 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. 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.

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



## Jasmine | 28-year-old with CAH

- Thinking about her future and wonders if her high androgen levels will affect her fertility
- Steroid: hydrocortisone
  - Dose: 3×/day (daily total, 32 mg)
- Androstenedione: elevated (450 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)



## Amy | 52-year-old with CAH

- Has struggled for years with osteoporosis, weight gain, and high cholesterol, which her doctor thinks are related to her high steroid doses
- Steroid: hydrocortisone
  - Dose: 2×/day (daily total, 30 mg)
- Androstenedione: within target range for post-menopausal women (75 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 doctor about what is an appropriate level for you based on your age, gender, and other factors.**

17-OHP=17-hydroxyprogesterone.

### SELECT IMPORTANT SAFETY INFORMATION

**Before taking CRENESSITY, tell your healthcare provider about all of your medical conditions including if you:** are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

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

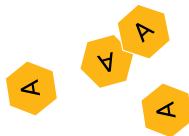
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# Managing CAH with steroids alone is challenging

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

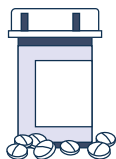
For people with CAH, low cortisol can also cause too many **androgens**. When the adrenal glands can't make cortisol, they end up making the hormone they *can* make—androgens. So a byproduct of not being able to make cortisol is too many androgens.



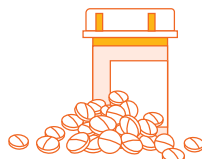
## What are androgens?

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.

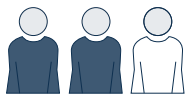
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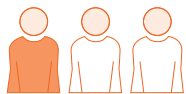
# Treatment with high-dose steroids alone can come at a cost

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 CAH treatment plan.

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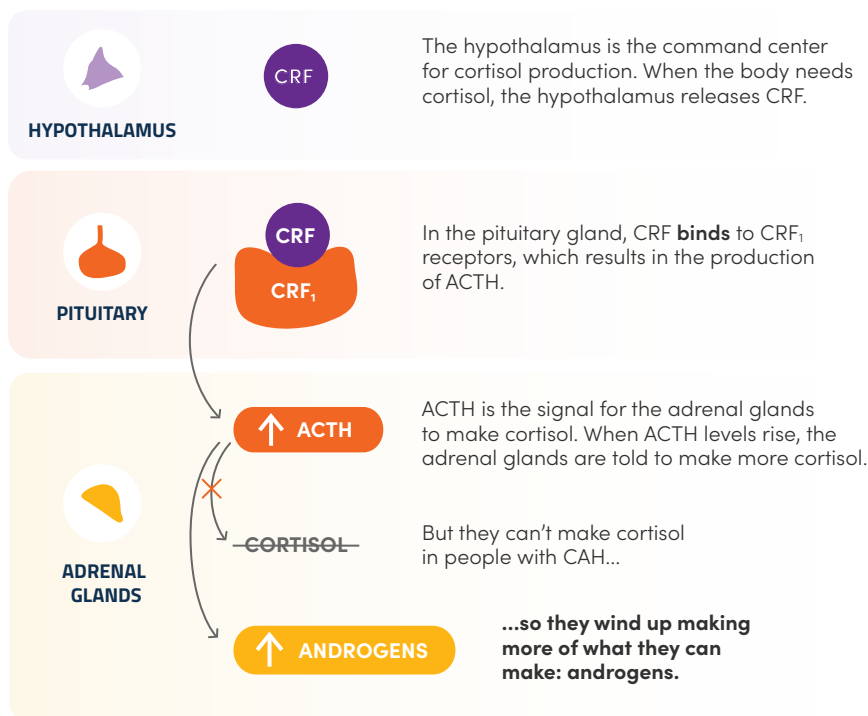
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# Treatment with CRENESSITY is a cutting-edge way to manage androgens

## 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 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.

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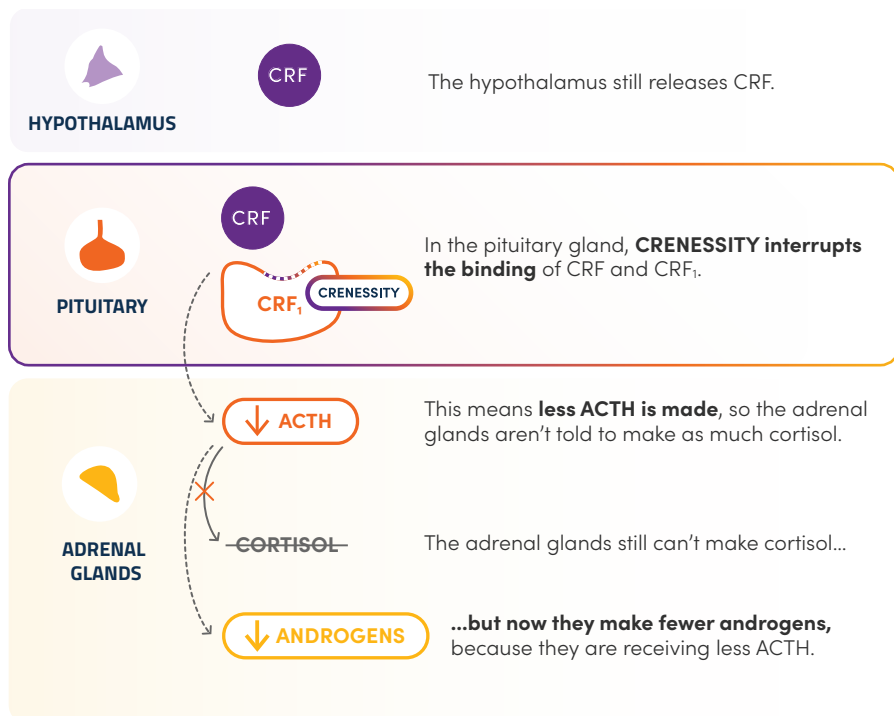
**Allergic reactions.** Symptoms of an allergic reaction include tightness of the throat, trouble breathing or swallowing, swelling of the lips, tongue, or face, and rash. If you have an allergic reaction to CRENESSITY, get emergency medical help right away and stop taking CRENESSITY.

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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

**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. 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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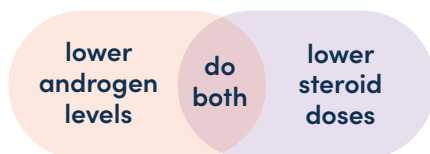




# Tested in the largest clinical study program for a classic CAH treatment

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

## The study in adults included 182 participants aged 18 years and older with classic CAH.

At the start of the study, all participants had to be taking hydrocortisone, prednisone, dexamethasone, or a similar steroid at a dose greater than the range needed to replace cortisol.



122 took CRENESSITY



60 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 24 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



~8x

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

~37x

**greater 17-OHP improvement** in adults taking CRENESSITY compared with those taking placebo<sup>†</sup>

## Steroid doses were lowered significantly



~2x

**greater steroid dose reduction** in adults taking CRENESSITY compared with those taking placebo<sup>‡</sup>

63%

**of adults were able to lower their steroid doses** to the range needed just to replace cortisol while androgen levels stayed the same or improved<sup>§</sup>

Steroid doses were lowered under careful supervision of doctors. CRENESSITY does not address cortisol deficiency. People taking CRENESSITY should continue taking steroids to replace missing cortisol.

\*Androstenedione levels were reduced by 299 ng/dL in adults taking CRENESSITY compared with an increase of 46 ng/dL with placebo.

<sup>†</sup>17-OHP levels were reduced by 5994 ng/dL in adults taking CRENESSITY compared with a reduction of 154 ng/dL with placebo. Unlike androstenedione, the 17-OHP information was assessed differently. Please talk to your doctor about what this means for you.

<sup>‡</sup>Adults treated with CRENESSITY were able to reduce their steroid dose by 27% from the beginning of the study compared with 10% for placebo.

<sup>§</sup>The cortisol replacement range was less than or equal to 20 mg/day (11 mg/m<sup>2</sup>/day) hydrocortisone (or equivalent doses for prednisone or dexamethasone). A total of 18% of adults taking placebo were able to lower their steroid doses to the range needed just to replace cortisol while androgen levels stayed the same or improved.

**After the placebo period of the study ended, 174 of the 182 adults (96%) chose to continue in the study, with all participants taking CRENESSITY.**



**Ask your doctor how CRENESSITY can help 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 adults



**Tiredness, headache, dizziness, joint pain, back pain, decreased appetite, and muscle pain** were the most common side effects in adults taking CRENESSITY.



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



**96% of adults taking CRENESSITY** completed the ~6-month (24-week) study.



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

**In the CAHtalyst™ Adult clinical study, two patients taking CRENESSITY experienced adrenal crisis. No patients on placebo experienced adrenal crisis; however, one did experience adrenal insufficiency.**

**Please talk to your doctor about how to manage your 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 restlessness, apathy, dyspepsia, nausea, and vomiting.

## SELECT IMPORTANT SAFETY INFORMATION

**Before taking CRENESSITY, tell your healthcare provider about all of your medical conditions including if you:** are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

**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 is a capsule taken by mouth twice daily with morning and evening meals.

100  
mg  $\times 2$

All adults aged 18 years and older take 100 mg twice daily (200 mg total each day).



Ask your doctor if it's possible to time your steroid doses with your 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 your regular dosing schedule.

- You should take CRENESSITY exactly as your doctor tells you to
- Talk to your doctor before stopping CRENESSITY
- Do not stop or change your steroid dosing unless your doctor says to



**Confirm your next appointment with your doctor and have your questions answered about CRENESSITY.**

## 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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# Discuss changes to your steroid regimen with your doctor

**Because CRENESSITY lowers androgens, your doctor may reduce your steroid dose.**

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

## Jasmine's Story

### | 28-year-old with CAH

- Has been taking CRENESSITY for almost a year
- Over the course of a few months, her doctor lowered her daily hydrocortisone dose by 10 mg per day, from 32 mg to 22 mg, and changed her dosing from 3×/day to 2×/day
- Her androstenedione levels were elevated when she started CRENESSITY but are now in a range her doctor thinks is right for her
- Her levels of testosterone, a type of androgen, also declined. She and her doctor continue to talk about what that may mean for her in the future



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In addition to lower steroid doses, many adults taking CRENESSITY were able to move to fewer doses per day or milder types of steroids.

Nearly

9/10

adults taking CRENESSITY and dexamethasone were able to **switch to a dexamethasone-free regimen**, compared to 4/10 taking placebo.

Almost

4/10

adults taking CRENESSITY and hydrocortisone were able to **take fewer doses of hydrocortisone each day**, compared to ~1/10 taking placebo.

3/10

adults taking CRENESSITY were able to **switch their steroid from prednisone\* to hydrocortisone**, compared to ~1/10 taking placebo.

\*Or related steroids (eg, prednisolone, methylprednisolone) with or without hydrocortisone.



Ask your doctor about reevaluating your steroid type and dosing schedule after starting on CRENESSITY.

## Patrick's Story

### | 38-year-old with CAH

- Has been taking CRENESSITY for 6 months
- His doctor switched him to hydrocortisone 3x/day from dexamethasone
- His androstenedione levels were within target range when he started CRENESSITY and were still within range on his most recent lab report, even with his change in steroid regimen



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## NEUROCRINE ACCESS SUPPORT

# Dedicated support available for your journey with CRENESSITY

### Your Care Coordinator



Once you are 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 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 prescription.



Neurocrine Access Support is more than just help with your medication. It's a comprehensive program designed to ensure you have everything you need 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 adults taking CRENESSITY were tiredness, headache, dizziness, joint pain, back pain, decreased appetite, and muscle pain.



## 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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