

Taking the next step with CRENESSITY

Real people. Different ages. Different steroids.











Discover how they each found a path to lower steroid doses with CRENESSITY

The profiles in this brochure are based on real experiences from the CAHtalystTM studies. Names and personal details have been changed. Your or your child's treatment may differ—even if age or steroid type is the same. Never change steroid doses without talking to your doctor.

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 6 and Patient Information.



See how real people with classic CAH worked with their doctors to lower their steroid doses after CRENESSITY helped improve or maintain androgen control during the CAHtalyst™ clinical studies.

After starting CRENESSITY, your care team will help you take the next step while keeping your unique needs in mind. If you or your child is taking high-dose steroids, this may include creating a personalized plan to gradually lower your steroid doses over the course of many months.

Everyone's treatment journey is different.

To guide the pace and timing of steroid dose reductions, androgen levels will be measured after taking CRENESSITY for at least 4 weeks.

Remember: You'll always continue to take steroids while taking CRENESSITY. Adrenal insufficiency remains an important risk with CAH and can occur if you are not taking enough steroids for your body's cortisol needs.

The Clinical Studies: A Quick Refresher

In clinical studies, CRENESSITY helped children and adults improve or maintain androgen control, allowing them to lower their steroid doses.

- In children ages 4 and older: After 4 weeks, androstenedione (androgen) levels dropped by an average of 197 ng/dL with CRENESSITY and increased by 71 ng/dL in those taking placebo. After 28 weeks, steroid doses were reduced by an average of 18% with CRENESSITY and increased by 6% for those taking placebo
- In adults: After 4 weeks, androstenedione levels dropped by an average of 299 ng/dL with CRENESSITY and increased by 46 ng/dL in those taking placebo. After 24 weeks, steroid doses were reduced by an average of 27% with CRENESSITY and 10% for those taking placebo



OLIVIA | 5-year-old with classic CAH*

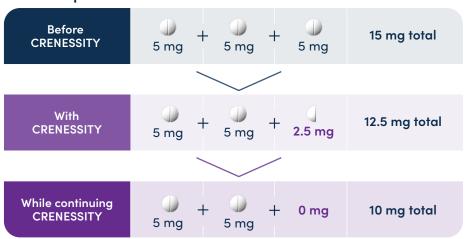
Before CRENESSITY

- Olivia was taking hydrocortisone 3 times a day
- Her androgen levels were within her target range
- She and her mom wanted to decrease her daily steroid dose

With CRENESSITY

 Olivia's androgens stayed within her target range, so her doctor started decreasing her evening steroid dose

Olivia's path to lower steroid doses



With CRENESSITY, now Olivia takes hydrocortisone only 2 times per day and takes 5 mg (33%) less in total.

As Olivia grows, her body's cortisol needs will grow too, and her doctor will adjust her steroid dose accordingly.

SELECT IMPORTANT SAFETY INFORMATION (continued)

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.

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CALEB | 12-year-old with classic CAH*

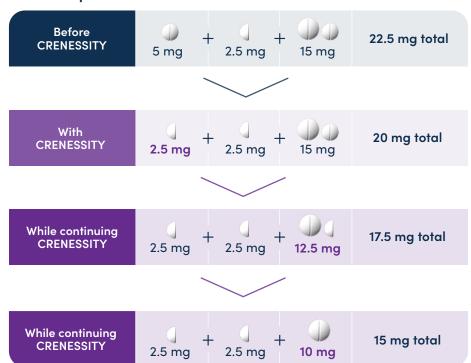
Before CRENESSITY

- Caleb was taking 22.5 mg of hydrocortisone each day
- He was struggling with both high androgen levels and the effects of high-dose steroids

With CRENESSITY

 Caleb's androgen levels went down, so his doctor decided to begin lowering his steroid dose

Caleb's path to lower steroid doses



With CRENESSITY, Caleb was able to lower his hydrocortisone dose by 7.5 mg or 33% daily.

Caleb's cortisol needs will grow as he grows, so his doctor will adjust his steroid dose accordingly.



Partner with your doctor to create a plan that aligns with your or your child's specific treatment goals, whether it be lowering the dose of your current steroid or switching to a milder type of steroid.

Keep in mind that even with a lower daily steroid dose, you'll still need the same amount of total steroid during illness, injury, or surgery that you did before lowering your daily dose. Talk with your doctor about any changes to your stress dosing plan—for example, 4× your daily dose rather than 3×, or dosing more frequently than before.

SELECT IMPORTANT SAFETY INFORMATION (continued)

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)





AARON 18-year-old with classic CAH*

Before CRENESSITY

- Aaron was taking dexamethasone once a day
- He was looking to reduce his high androgens and take less steroids overall
- While he and his doctor talked about switching to a milder type of steroid, Aaron did not want to take a steroid more than once a day and preferred to stick with dexamethasone

With CRENESSITY

 Aaron's androgen levels were brought under control, so his doctor was ready to decrease his steroid dose

Aaron's path to lower steroid doses

| Before CRENESSITY | 0.50 mg total |
|-----------------------------|---------------|
| | |
| With CRENESSITY | 0.40 mg total |
| | |
| While continuing CRENESSITY | 0.35 mg total |

With CRENESSITY, Aaron lowered his dexamethasone dose by 0.15 mg or 30% daily.



If you or your child is lowering steroid doses and experiences symptoms such as tiredness, nausea, aches, sleep issues, or mood changes, they may be associated with steroid withdrawal. Let your care team know. These symptoms usually improve within a few weeks.



JAMES | 29-year-old with classic CAH*

Before CRENESSITY

- James was taking prednisone 2 times a day
- His androgen levels were above the target range for his age

With CRENESSITY

 James's androgen levels dropped to the target range for his age, so his doctor decided he could begin to phase out one dose of prednisone per day

James's path to lower steroid doses

| Before CRENESSITY | + 5 mg | 2 mg | 7 mg total | | |
|--------------------------------|--------|-----------|------------|--|--|
| | | | | | |
| With CRENESSITY | + 5 mg | ① 1 mg | 6 mg total | | |
| | | | | | |
| While continuing CRENESSITY | 5 mg + | 0 mg | 5 mg total | | |

With CRENESSITY, James lowered his prednisone dose by 2 mg or ~30% daily, allowing him to take it only once a day.

SELECT IMPORTANT SAFETY INFORMATION (continued)

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.





KIERRA | 35-year-old with classic CAH*

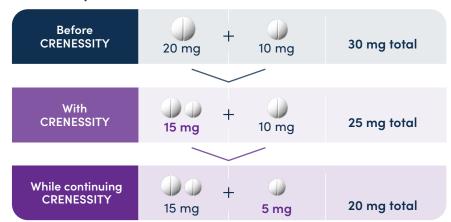
Before CRENESSITY

- Kierra was taking hydrocortisone 2 times a day
- Her goal was to lower her high androgen levels and take a lower dose of steroids

With CRENESSITY

 Kierra's androgen levels dropped, so her doctor recommended taking the next step and started lowering her steroid dose

Kierra's path to lower steroid doses



With CRENESSITY, Kierra's hydrocortisone dose decreased by 10 mg or 33%.



Now that you've seen how others have lowered their steroid dose while on CRENESSITY, it's time to work with your doctor to create a personalized plan that fits your or your child's treatment goals.

Questions to ask your doctor:

- When should we run labs for androgens (such as androstenedione and 17-OHP)?
- How do you decide when it's the right time for me to start lowering my steroid dose, and what happens next?
- How do you determine future dose changes?
- What signs should I look out for as the dose changes?
- How will my stress dosing plan be adjusted?



Explore <u>additional resources on our site</u> to help you on your CRENESSITY journey.

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17-OHP=17-hydroxyprogesterone.

SELECT IMPORTANT SAFETY INFORMATION (continued)

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.

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 or call 1-800-FDA-1088.

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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 <u>Prescribing Information</u>.

