CRENESSITY DOSING GUIDE



CRENESSITY is taken by mouth twice daily for steady levels around the clock. Twice-daily dosing means androgen levels stay more consistent throughout the day and night.

Follow directions from your or your child's doctor on how to take CRENESSITY.

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Adults aged 18 years and older take 100 mg twice daily (200 mg total each day). For children and teens, CRENESSITY dosing is based on weight. Explore more below.	Take CRENESSITY with morning and evening meals.	Ask your or your child's doctor if it's possible to time steroid doses with CRENESSITY doses.	Take CRENESSITY exactly as your or your child's doctor tells you to.	
Talk to your or your child's doctor before stopping CRENESSITY				

In children and teens, 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)	

For children, CRENESSITY comes in capsules or as an oral solution (liquid). If prescribed CRENESSITY oral solution, use the oral dosing syringe provided by the pharmacist to measure the correct dose. Refer to the Instructions for Use included with the prescription for more information.

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 full <u>Prescribing Information</u>.

What if a dose is missed?

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

After starting CRENESSITY, your or your child's doctor may gradually begin to reduce the steroid dose while ensuring that you or your child still have enough steroids to meet cortisol needs.

Lowering steroid doses while taking CRENESSITY

- CRENESSITY does not treat cortisol insufficiency, so steroids are still needed
- Talk to your or your child's doctor about a plan to reduce steroid doses over time, and make sure to continue stress dosing when needed
- Lab values and clinical symptoms will help your or your child's doctor guide steroid dose reduction
- Talk to your or your child's doctor about what to expect and how to feel as the body adjusts to a lower steroid dose
- Do not stop or change steroid dose unless your or your child's doctor tells you to

Patients and caregivers share their CRENESSITY experiences

Watch real patients and caregivers tell their stories about starting CRENESSITY at <u>CRENESSITY.com</u>



Watch their stories

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IMPORTANT SAFETY INFORMATION

Do not take CRENESSITY if you:

Are allergic to crinecerfont, or any of the ingredients in CRENESSITY.

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.

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. 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 <u>www.fda.gov/medwatch</u> or call <u>1-800-FDA-1088</u>.

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>.



