



Models are for illustrative purposes only.

## Macrilen™ Test Discussion Guide

Important facts about GH testing for you  
and your patients

GH=growth hormone.

### **Indication and Limitation of Use**

Macrilen™ (macimorelin) 60 mg for oral solution is indicated for the diagnosis of adult growth hormone deficiency (AGHD).

- The safety and diagnostic performance of Macrilen™ have not been established for subjects with a body mass index (BMI)  $>40 \text{ kg/m}^2$

**Please see Important Safety Information throughout.**

Please see Prescribing Information at  
<https://www.novo-pi.com/macrilen.pdf>.



**Macrilen™** 60 mg  
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# How to Use This Discussion Guide

This guide can help you talk to your patients once you make the decision to test for GHD. Inside you will find information about Macrilen™: what it is, how it works, and what to discuss with your patients before and after administering the test.

GHD=growth hormone deficiency.

## Important Safety Information

### Warnings and Precautions

- **QT Prolongation:** Macrilen™ causes an increase of about 11 msec in the corrected QT (QTc) interval. QT prolongation can lead to development of torsade de pointes-type ventricular tachycardia with the risk increasing as the degree of prolongation increases. The concomitant use of Macrilen™ with drugs that are known to prolong the QT interval should be avoided

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# What Is Macrilen™?

Macrilen™ is the first and only FDA-approved oral test for the diagnosis of AGHD, a condition that typically presents as a variety of growth abnormalities.<sup>1,2</sup> Macrilen™ is a prescription test that comes in powder form and is mixed with water to form a solution patients can drink to help you determine if they have AGHD.<sup>1</sup>



## 90-minute total test time<sup>1</sup>

Blood will be drawn at 30, 45, 60, and 90 minutes



## Routine supervision<sup>1</sup>

The doctor or nurse will check on the patient throughout the test

## Important Safety Information

### Warnings and Precautions

- **Potential for False Positive Test Results with Use of Strong CYP3A4 Inducers:** Concomitant use of strong CYP3A4 inducers with Macrilen™ can decrease macimorelin plasma levels significantly and thereby lead to a false positive result. Strong CYP3A4 inducers should be discontinued and enough time should be given to allow washout of CYP3A4 inducers prior to test administration

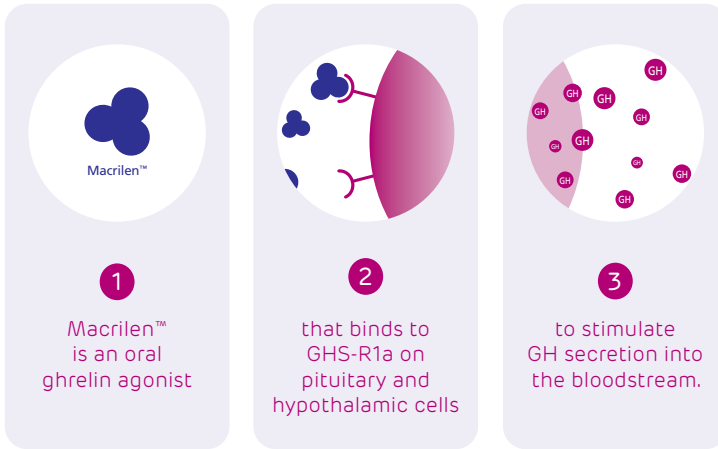
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# How Does Macrilen™ Work?

Macrilen™ activates the production of GH in the pituitary gland. The pituitary gland is important because it controls other hormone glands in the body.<sup>1,3</sup> Macrilen™ acts in the body like the endogenous hormone, ghrelin, by latching on to the growth hormone receptor. It then turns on the receptors of other glands to stimulate GH release into the circulatory system.<sup>1,4</sup>



Once you and your patient decide it's time to take the Macrilen™ test, you can use the following pages to guide your discussions on what to expect during and after the test.

GHS-R1a=growth hormone secretagogue receptor 1a.

## Important Safety Information

### Warnings and Precautions

- Potential for False Negative Test Results in Recent Onset Hypothalamic Disease:** Adult growth hormone (GH) deficiency caused by a hypothalamic lesion may not be detected early in the disease process. Macimorelin acts downstream from the hypothalamus and macimorelin stimulated release of stored GH reserves from the anterior pituitary could produce a false negative result early when the lesion involves the hypothalamus. Repeat testing may be warranted in this situation

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# Before the Test<sup>1</sup>

Macrilen™ is an innovative approach to diagnosing AGHD. Its dosing is based on the patient's weight. First weigh your patient so you can order the appropriate number of Macrilen™ pouches ( $\leq 120$  kg = 1 pouch;  $>120$  kg = 2 pouches). When they come in for the test, be sure to weigh them again so that the proper dose can be determined (ie, a patient weighing 70 kg will need 70 mL of the prepared Macrilen™ solution).

## Remember to also:

- Find out if they are breastfeeding, pregnant, or trying to get pregnant.<sup>1</sup>
- Discuss all the medications they may be taking. They might need to stop taking certain medications that could affect the test results.<sup>1</sup>
- Remind them to fast for at least 8 hours before the test **(no eating or drinking anything except water).**<sup>1</sup>

## Important Safety Information

### Adverse Reactions

- The most common adverse reactions are dysgeusia, dizziness, headache, fatigue, nausea, hunger, diarrhea, upper respiratory tract infection, feeling hot, hyperhidrosis, nasopharyngitis, and sinus bradycardia

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# During the Test<sup>1</sup>

The Macrilen™ test is completed in 3 main steps.



## Drink

The patient must drink the entire Macrilen™ solution within 30 seconds and be closely observed throughout the test.



## Draw

After drinking the Macrilen™, blood samples will be drawn 4 times—at 30, 45, 60, and 90 minutes.



## Diagnose

The doctor will prepare and send the samples to the lab for testing.

# After the Test<sup>1,5</sup>

Once the test results are ready, review them with your patient to agree on next steps. The test provides a more complete picture of your patient's overall health, so together you can determine whether treatment should be initiated.

If your patient is diagnosed and treatment is initiated, monitor them closely until maintenance levels are met, and then every 6 months thereafter.<sup>5</sup>

If the test results don't confirm diagnosis of AGHD, further testing may be required.<sup>1</sup>

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# Frequently Asked Questions About Macrilen™

The following are questions patients typically ask about Macrilen™ and simple answers you can provide.<sup>1</sup>

## How is Macrilen™ taken?

Macrilen™ is an oral solution. For best results, drink all the solution within 30 seconds.

## How many blood draws should I expect?

Blood will be drawn 4 times—at 30, 45, 60, and 90 minutes after you drink the solution.

## How long does the test take?

The test will be over in 90 minutes.

## Will there be someone there with me?

You will receive medical supervision while you are taking the test.

## Are there any patients who can't take the Macrilen™ test?

The test can be taken by most patients who display symptoms of AGHD, except those who have a BMI of  $>40$  kg/m<sup>2</sup>. However, there are some medications that should be stopped before administering the test. Please be sure to tell your doctor about any medications you are currently taking.

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**What are the most common side effects?**

You may experience any of these side effects: a changed sense of taste, dizziness, headache, fatigue, nausea, hunger, diarrhea, upper respiratory tract infection, feeling hot, excessive sweating, sore nose and throat, and decreased heart rate.

**How does Macrilen™ help with diagnosis of AGHD?**

All of the blood samples drawn during the test will be analyzed in a lab. Once the results are in, your HCP can confirm or exclude a diagnosis of AGHD.

**Is Macrilen™ covered by insurance?**

Novo Nordisk is committed to supporting patient access to Macrilen™. With the Macrilen™ Commercial Co-pay Savings Program, eligible patients may pay as little as \$0 (with an annual co-pay assistance of \$1000). Through our Patient Assistance Program, patients without health insurance coverage may be eligible to receive Macrilen™ at no cost. Contact NovoCare® to find out how they can help you.

Remember, your patients may benefit from having a more complete picture of their health and knowing the potential effects of AGHD. Help them understand their treatment options, so together you can make an informed decision about testing and treatment.

If you or your patients would like more information on Macrilen™, call 1-844-622-2443.

**Important Safety Information****Warnings and Precautions**

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**References:** 1. Macrilen [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; 2019. 2. Yuen KCJ, Tritos NA, Samson SL, Hoffman AR, Katznelson L. American Association of Clinical Endocrinologists and American College of Endocrinology disease state clinical review: update on growth hormone stimulation testing and proposed revised cut-point for the glucagon stimulation test in the diagnosis of adult growth hormone deficiency. *Endocr Pract.* 2016;22(10):1235-1244. 3. Garcia, JM, Swerdloff R, Wang C, et al. Macimorelin (AEZS-130)-stimulated growth hormone (HG) test: validation of a novel oral stimulation test for the diagnosis of adult GH deficiency. *J Clin Endocrinol Metab.* 2013;98(6):2422-2429. 4. Agrawal V, Garcia JM. The macimorelin-stimulated growth hormone test for adult growth hormone deficiency diagnosis. *Expert Rev Mol Diagn.* 2014;14(6):647-654. 5. Molitch ME, Clemmons DR, Malozowski S, Merriam GR, Vance ML, Endocrine Society. Evaluation and treatment of adult growth hormone deficiency: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2011;96(6):1587-1609.

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