H.P. Acthar\textsuperscript{®} Gel (repository corticotropin injection) is indicated for the reduction of proteinuria in people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or that due to lupus erythematosus (lupus).

Please see Important Safety Information on pages 16–18, and the accompanying full Prescribing Information.
Important Safety Information

You should not take Acthar if you have:

- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral
- Eye problems, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of ulcers
- Heart problems
- High blood pressure
- Allergies to pig-derived proteins
- Been recently given a vaccine or are about to take one
- Suspected congenital infections (in children under 2 years of age)
- A condition where your adrenal glands produce either too much of certain hormones (as with Cushing’s syndrome), or not enough (adrenal insufficiency)

Tell your doctor if you have any of these conditions or any other health problems.

Please see additional Important Safety Information on pages 16–18, and the accompanying full Prescribing Information.
Welcome to treatment with Acthar.

Acthar is an FDA-approved medication your healthcare provider prescribed to help treat your proteinuria due to nephrotic syndrome for a chance at remission.

Although the best source of information about your condition is always your healthcare provider, this brochure can help you start to understand more about proteinuria, the different symptoms you might have, and how to get started with Acthar.

Read on to learn more.
What is nephrotic syndrome?

Nephrotic syndrome ("nef-rah-tik sin-drohm") is a condition that describes a group of signs and symptoms that often occur together in the kidneys. The kidneys are an important organ in your body because they help filter materials from your blood. When they are not working properly, different symptoms can occur.

The most common signs and symptoms of nephrotic syndrome are:

- Proteinuria: high amounts of protein in the urine
- Hypoalbuminemia: low amounts of albumin, a type of protein, in the blood
- Edema: a buildup of fluids in body tissues or skin that can cause swelling
- Hyperlipidemia: a high blood level of lipids, or cholesterol

What is proteinuria of nephrotic syndrome?

Proteinuria ("proh-teen-yoo-ree-uh") is a condition that occurs when the filters in your kidneys do not work properly, causing protein to "leak" into your urine. These filters are found in the glomeruli ("gloh-mair-yoo-lie") and are made of interlocking fingerlike structures known as podocytes ("poh-doh-sights").

Podocytes keep important materials your body needs in, and allow waste to pass through the pores. In people with proteinuria, the structure of the podocytes is changed so blood proteins—normally too big to pass through—escape and “spill out” into the urine. While having some protein in the urine is normal, too much for too long can be a warning sign of a more serious problem.
What are some of the signs and symptoms of proteinuria?

- Foamy-looking urine
- Swelling of the face or ankles
- Weight gain
- Fatigue

It is important to remember that Acthar is indicated to treat excess protein in the urine; it is not indicated to treat other symptoms of nephrotic syndrome.

### Proteinuria of nephrotic syndrome can be associated with a variety of conditions including:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membranous nephropathy (MN)</td>
<td>Membranoproliferative glomerulonephritis (MPGN)</td>
</tr>
<tr>
<td>Focal segmental glomerulosclerosis (FSGS)</td>
<td>IgA nephropathy (IgAN)</td>
</tr>
<tr>
<td>Minimal change disease (MCD)</td>
<td>Lupus nephritis (LN)</td>
</tr>
</tbody>
</table>

Acthar can be used to treat proteinuria that occurs when you have one of these kidney conditions. If you have proteinuria, you and your doctor should work together to create a plan that may help lower the level of protein in your urine.

### Important Safety Information

- Never inject Acthar directly into a vein, always take Acthar as prescribed by your doctor
- Never stop treatment suddenly unless your doctor tells you to
- Try not to miss any scheduled doctor’s appointments as it is important for the doctor to monitor you while taking Acthar

Please see additional Important Safety Information on pages 16–18, and the accompanying full Prescribing Information.
What is Acthar?

H.P. Acthar® Gel (repository corticotropin injection), commonly known as Acthar, is a prescription medication. Acthar was FDA approved in 1952 for multiple conditions, including proteinuria due to nephrotic syndrome.

Acthar is indicated to reduce proteinuria in people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or due to lupus, giving them a chance at remission.

Acthar is:
- FDA approved to reduce proteinuria in nephrotic syndrome
- Medicine that contains adrenocorticotropic hormone (ACTH), a naturally occurring hormone produced in your body
- Not a steroid

Why has my healthcare provider prescribed Acthar for me?

After your discussions together, your healthcare provider reviewed your individual medical assessment and determined that Acthar is an option for the treatment of your proteinuria. The goal of treatment is to lower levels of protein in your urine.

Proteinuria of nephrotic syndrome is a rare condition, but approximately 5,300 patients with similar treatment goals have been prescribed Acthar for a chance at remission.**†

Only your healthcare provider can determine if Acthar is right for you. It is important to follow Acthar treatment as prescribed by your healthcare provider.

*Based solely on prescription data. The number of patients treated and any clinical outcomes of such patients are unknown.
How does Acthar work?*

Acthar is not a steroid, and is thought to work differently than steroids. Acthar is believed to work by helping your body produce its own natural steroid hormones. Natural steroid production helps your body regulate inflammation.

Acthar is also believed to work with your immune system throughout various parts of your body, including in your kidneys.

*While the exact way that Acthar works in the body is unknown, further studies are being conducted. This information is based on laboratory data, and how it relates to patient benefit is unknown.

Important Safety Information

- **Increased risk of infections.** You may be more likely to get new infections. Also, old infections may become active. Before and during treatment, tell your doctor if you see any signs of an infection

- **Adrenal gland changes.** Sometimes, especially when taking Acthar long term, your adrenal gland may produce too much of a hormone called cortisol

Always talk to your doctor before you stop taking Acthar.

Please see additional Important Safety Information on pages 16–18, and the accompanying full Prescribing Information.
How do I administer Acthar?

- Acthar is an injection that can be given either:
  - Under the skin (subcutaneously)
  - Or into the muscle (intramuscularly)
- Acthar can be taken when and where is best for you; it can be self-injected or given to you by a friend, family member, or caregiver, as well as your healthcare provider
- Acthar is designed to provide a prolonged release of medication once it has been injected

Your healthcare provider will describe how to correctly inject Acthar and tell you what dose is appropriate for you.

See page 14 to learn about how Acthar Home Injection Training Services (Acthar HITS) is available to help you with injecting Acthar.
What can I expect with Acthar?

- Acthar may lower the amount of protein in your urine to a more normal level; it will not cure your condition
- Everyone is different, so responses to treatment will vary
- Remember to continue to take Acthar exactly as prescribed, even if you feel better. Only your healthcare provider can determine when or if it is appropriate to change your treatment

Contact your healthcare provider with any questions you have about treatment.

What is important to know about Acthar?

- Acthar is a medicine that affects a patient’s immune system, and therefore patients may be more likely to get new infections, or inactive infections may become active
- Common side effects of Acthar can be similar to those seen with steroid medicines and may include:
  - Fluid retention
  - Changes in blood sugar
  - Increased blood pressure
  - Behavior or mood changes
  - Increased appetite
  - Weight gain

Important Safety Information

- **Increased blood pressure, body salt, and fluid levels.** Your doctor may check your blood pressure while you are being treated with Acthar. He or she may recommend some changes to your diet, such as eating less salt and taking certain supplements
- **Unpredictable response to vaccines.** Talk to your doctor about which vaccines are safe to use when you are taking Acthar
- **Masking other conditions.** Acthar may hide symptoms of other diseases. This can make it more difficult for your doctor to make a diagnosis if something else is going on

Please see additional Important Safety Information on pages 16–18, and the accompanying full Prescribing Information.
What if I miss a dose of Acthar?

If you have missed a dose or taken more than prescribed, contact your healthcare provider for instructions about how to take your next dose of Acthar.

Can I take other medications while taking Acthar?

- Tell your healthcare provider about any other medications you are taking, and he or she will instruct you on any changes you will need to make with them
- Continue taking your other treatments as prescribed by your healthcare provider

How should I store Acthar?

Acthar should be kept refrigerated (36°F–46°F or 2°C–8°C) between uses. Acthar is a gel when refrigerated, but changes to liquid form at room temperature. Remember to only inject Acthar once it has reached room temperature; this will help make the injection more comfortable for you.

If you will be traveling, it is important that your Acthar medication is kept refrigerated. To find more information for travelers with medical conditions, visit the TSA website at tsa.gov or call TSA Cares at 1-855-787-2227.
Can I get financial assistance for Acthar?

We know that working with your insurance company and paying for medication can sometimes be difficult, so the Acthar Support & Access Program (A.S.A.P.) was created to work directly with your healthcare provider and insurance company to help secure the best coverage with the lowest possible copay.

A.S.A.P. was created by the distributor of Acthar in an effort to help ensure that all eligible patients who need Acthar can get it.

Read on for more information about A.S.A.P.

Important Safety Information

The most common side effects of Acthar are similar to those of steroids. They include:

- Fluid retention
- Changes in blood sugar
- Increased blood pressure
- Behavior and mood changes
- Changes in appetite and weight

Specific side effects in children under 2 years of age include:

- Increased risk of infections
- Increased blood pressure
- Irritability
- Symptoms of Cushing’s syndrome
- Cardiac hypertrophy (thickening of the heart muscle)
- Weight gain

The above side effects may also be seen in adults and children over 2 years of age.

These are not all the possible side effects of Acthar.

Please see additional Important Safety Information on pages 16–18, and the accompanying full Prescribing Information.
Acthar Support & Access Program (A.S.A.P.)

A.S.A.P. is a no-cost resource provided by the distributor of Acthar that:

- Works directly with your healthcare provider to help with insurance coverage
- Contacts your insurance company to help try to secure the best insurance at the lowest possible copay

A.S.A.P. helps make Acthar affordable for patients by identifying sources of financial assistance including:

- Acthar offered at no cost for eligible uninsured and underinsured patients*
- Helping to identify other sources of financial assistance, such as additional copay assistance, for qualified patients in need who do not meet requirements for the listed programs†

To learn more about A.S.A.P., or to see if you are eligible for financial assistance, visit Acthar.com or call A.S.A.P. at 1-888-435-2284.

Mallinckrodt has donated more than $774 million in Acthar at no cost to patients‡

$0 COPAY for qualified patients with commercial or private insurance§

*Program administered via a third-party organization.
†Program administered via an independent charitable organization.
‡Dollar figure refers to commercial value of free drug based on data through June 2015.
§Data on file: RD-001-00. Mallinckrodt ARD, Inc.
||Up to a maximum copay benefit of $25,000 per person is available per calendar year. This program is not for patients receiving prescription reimbursement under any federal-, state-, or government-funded insurance programs or where prohibited by law. Additional terms and conditions and eligibility criteria apply.
A.S.A.P. helped with the delivery and financial sides of getting my medicine. I can’t tell you how much I appreciated the help. It helped me to focus on my health and my family.

Getting your medication: Who does what

Your healthcare provider sends your Acthar prescription to A.S.A.P.

A.S.A.P. works with your insurance company and a Specialty Pharmacy
- A.S.A.P. may call you for information
- The Specialty Pharmacy will call you to schedule delivery

Acthar is delivered to your door

Please see Important Safety Information on pages 16–18, and the accompanying full Prescribing Information.
What if I need help with my first injection?

You can sign up for Acthar Home Injection Training Services (Acthar HITS) and have a licensed nurse visit you at your home to provide you or your caregiver training on how to administer Acthar. If you have any questions about administration, the nurse is there to answer them.

Acthar HITS is a no-cost service made available by the maker of Acthar. Your healthcare provider can enroll you in the program or you can call A.S.A.P. at 1-888-435-2284 for more information.
Who can I talk to if I have questions about my condition or Acthar treatment?

If you have questions about Acthar treatment, the Patient & Acthar Coaching Team (ActharPACT) is there to support you.

ActharPACT is a no-cost resource that provides personalized support and education to patients on Acthar. If you enroll in ActharPACT you can receive:

- Access to a phone help line staffed by registered nurses trained to answer questions about kidney disease, proteinuria, and Acthar therapy
- Phone, mail, and/or online follow-up support and education during therapy as frequently or infrequently as you request, with the ability to cancel the service at any time

If you would like to get a personal coach, your healthcare provider can enroll you, or you or your caregiver can call 1-888-419-8482 or visit ActharPACT.com/enroll.

Please see Important Safety Information on pages 16–18, and the accompanying full Prescribing Information.
Important Safety Information

Acthar is injected beneath the skin or into the muscle.

Who should NOT take Acthar?
You should not take Acthar if you have:

- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral
- Eye problems, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of ulcers
- Heart problems
- High blood pressure
- Allergies to pig-derived proteins
- Been recently given a vaccine or are about to take one
- Suspected congenital infections (in children under 2 years of age)
- A condition where your adrenal glands produce either too much of certain hormones (as with Cushing’s syndrome), or not enough (adrenal insufficiency)

Tell your doctor if you have any of these conditions or any other health problems. Also, share with your doctor what medicines you are taking. Don’t forget to mention non-prescription medicines, vitamins, and herbal supplements.

What is the most important information I should know about Acthar?

- Never inject Acthar directly into a vein, always take Acthar as prescribed by your doctor
- Never stop treatment suddenly unless your doctor tells you to
- Try not to miss any scheduled doctor’s appointments as it is important for the doctor to monitor you while taking Acthar

Acthar can cause side effects similar to those with steroid treatments. While taking Acthar, tell your doctor right away if you have any of the symptoms listed here:

- Increased risk of infections. You may be more likely to get new infections. Also, old infections may become active. Before and during treatment, tell your doctor if you see any signs of an infection. Contact your doctor at the first sign of an infection or fever. Signs of infection are fever, cough, vomiting, or diarrhea. Other signs may be flu or any open cuts or sores
- **Adrenal gland changes.** When taking Acthar long term, your adrenal gland may produce too much of a hormone called cortisol, which may cause symptoms of Cushing’s syndrome, such as upper body fat, rounded “moon” face, bruising easily, or muscle weakness. Sometimes when you stop taking Acthar long term, your body may not produce enough cortisol on its own. This is called “adrenal insufficiency.” Your doctor may prescribe a steroid medicine to protect you until the adrenal gland recovers.

- **Increased blood pressure, body salt, and fluid levels.** Your doctor may check your blood pressure while you are being treated with Acthar. He or she may recommend some changes to your diet, such as eating less salt and taking certain supplements.

- **Unpredictable response to vaccines.** Talk to your doctor about which vaccines are safe to use when you are taking Acthar.

- **Masking other conditions.** Acthar may hide symptoms of other diseases. This can make it more difficult for your doctor to make a diagnosis if something else is going on.

- **Stomach or intestinal problems.** Acthar may put you at increased risk for bleeding from the stomach, or getting stomach ulcers. Tell your doctor if you have stomach pains, bloody vomit, bloody or black stools, excessive tiredness, increased thirst, difficulty breathing, or increased heart rate.

- **Changes in mood or behavior.** Taking Acthar can make you feel irritable or depressed. You may also have mood swings or trouble sleeping.

- **Worsening of other medical conditions.** If you have other conditions, such as diabetes or muscle weakness, you may find they get worse.

- **Eye problems.** It’s possible that you may develop certain eye conditions, such as cataracts, glaucoma, or optic nerve damage.

- **Allergic reactions.** Your body may develop antibodies or become sensitive when Acthar is used long term. Signs of allergic reaction in children are:
  - Skin rash
  - Swelling of the face, tongue, lips, or throat
  - Trouble breathing

- **Problems with growth and physical development.** Using Acthar long term can affect growth and physical development in children. This can be reversed when Acthar is no longer needed.

- **Bone density loss.** Acthar may cause osteoporosis at any age.

- **Potential harm to unborn baby.** Tell your doctor if you are pregnant or plan on becoming pregnant.

**Please see the accompanying full Prescribing Information.**
Important Safety Information (continued)

What are the most common side effects of Acthar?

The most common side effects of Acthar are similar to those of steroids. They include:

- Fluid retention
- Changes in blood sugar
- Increased blood pressure
- Behavior and mood changes
- Changes in appetite and weight

Specific side effects in children under 2 years of age include:

- Increased risk of infections
- Increased blood pressure
- Irritability
- Symptoms of Cushing’s syndrome
- Cardiac hypertrophy (thickening of the heart muscle)
- Weight gain

The above side effects may also be seen in adults and children over 2 years of age.

These are not all the possible side effects of Acthar.

Tell your doctor about any side effect that bothers you, or that does not go away. Call your doctor or pharmacist for medical advice about side effects. You may report side effects to the FDA. Call 1-800-FDA-1088 or visit fda.gov/medwatch. You may also report side effects by calling 1-800-778-7898.

Please see the accompanying full Prescribing Information.

For more information about Acthar, please visit ActharExcessProtein.com.