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Patient Information

GIOXIL-36® CAPSULES

Read this important information before you start taking GIOXIL-36 and each time you get a refill.

There may be new information. You may also find it helpful to share this information with your partner. This information does not take the place of talking with your healthcare provider. You and your healthcare provider should talk about GIOXIL-36 when you start taking it and at regular checkups. If you do not understand the information, or have questions, talk with your healthcare provider or pharmacist.

What Is The Most Important Information I Should Know About GIOXIL-36?
GIOXIL-36 can cause your blood pressure to drop suddenly to an unsafe level if it is taken with certain other medicines. You could get dizzy, faint, or have a heart attack or stroke.

Do not take GIOXIL-36 if you **take any medicines called “nitrates.”** Nitrates are commonly used to treat angina. Angina is a symptom of heart disease and can cause pain in your chest, jaw, or down your arm.

- Medicines called nitrates include nitroglycerin that is found in tablets, sprays, ointments, pastes, or patches. Nitrates can also be found in other medicines such as isosorbide dinitrate or isosorbide mononitrate. Some recreational drugs called “poppers” also contain nitrates, such as amyl nitrite and butyl nitrite.
- Ask your healthcare provider or pharmacist if you are not sure if any of your medicines are nitrates.

(See **“Who should not take GIOXIL-36?”**)

Tell all of your healthcare providers that you take GIOXIL-36. If you need emergency medical care for a heart problem, it will be important for your healthcare provider to know when you last took GIOXIL-36.

After taking a single tablet, some of the active ingredient of GIOXIL-36 remains in your body for more than 2 days.

The active ingredient can remain longer if you have problems with your kidneys or liver, or you are taking certain other medications (see **“Can Other Medicines Affect GIOXIL-36?”**).

Stop sexual activity and get medical help right away if you get symptoms such as chest pain, dizziness, or nausea during sex. Sexual activity can put an extra strain on your heart, especially if your heart is already weak from a heart attack or heart disease.

See also **“What Are The Possible Side Effects Of GIOXIL-36?”**

What Is GIOXIL-36?

GIOXIL-36 is a prescription medicine taken by mouth for the treatment of erectile dysfunction (ED) in men.

ED is a condition where the penis does not fill with enough blood to harden and expand when a man is sexually excited, or when he cannot keep an erection. A man who has trouble getting or keeping an erection should see his healthcare provider for help if the condition bothers him.

GIOXIL-36 helps increase blood flow to the penis and may help men with ED get and keep an erection satisfactory for sexual activity. Once a man has completed sexual activity, blood flow to his penis decreases, and his erection goes away. Some form of sexual stimulation is needed for an erection to happen with GIOXIL-36.

GIOXIL-36 does not:

- cure ED
- increase a man's sexual desire
- protect a man or his partner from sexually transmitted diseases, including HIV. Speak to your healthcare provider about ways to guard against sexually transmitted diseases.
- serve as a male form of birth control

GIOXIL-36 is only for men over the age of 18 who have ED, including men with diabetes or who have undergone prostatectomy

GIOXIL-36 is not for women or children.

GIOXIL-36 must be used only under a healthcare provider's care.

Who Should Not Take GIOXIL-36?

Do not take GIOXIL-36 if you:

- **take any medicines called "nitrates".**
- use recreational drugs called "poppers" like amyl nitrite and butyl nitrite. (See "**What Is The Most Important Information I Should Know About GIOXIL-36?**")

What Should I Tell My Healthcare Provider Before Taking GIOXIL-36?

GIOXIL-36 is not right for everyone. **Only your healthcare provider and you can decide if**

GIOXIL-36 is right for you. Before taking GIOXIL-36, tell your healthcare provider about all your medical problems, including if you:

- **are allergic to GIOXIL-36 or ADCIRCA™ or any of its ingredients.** See the end of this

leaflet for a complete list of ingredients in GIOXIL-36.

- **have heart problems** such as angina, heart failure, irregular heartbeats, or have had a heart

attack. Ask your healthcare provider if it is safe for you to have sexual activity. You should not take GIOXIL-36 if your healthcare provider has told you not to have sexual activity because of your health problems.

- **have low blood pressure or** have high blood pressure that is not controlled
- **have had a stroke**
- **have liver problems**

- **have kidney problems or require dialysis**
- **have retinitis pigmentosa**, a rare genetic (runs in families) eye disease
- **have ever had severe vision loss, including a condition called NAION**
- **have stomach ulcers**
- **have a bleeding problem**
- **have a deformed penis shape** or Peyronie's disease
- **have had an erection that lasted more than 4 hours**
- **have blood cell problems** such as sickle cell anemia, multiple myeloma, or leukemia

Can Other Medicines Affect GIOXIL-36?

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. GIOXIL-36 and other medicines may affect each other. Always check with your healthcare provider before starting or stopping any

medicines. Especially tell your healthcare provider if you take any of the following:*

- medicines called nitrates

(see **“What Is The Most Important Information I Should Know About GIOXIL-36?”**)

- medicines called alpha blockers. These include Hytrin® (terazosin HCl), Flomax® (tamsulosin HCl), Cardura® (doxazosin mesylate), Minipress® (prazosin HCl) or Uroxatral® (alfuzosin HCl). Alpha blockers are sometimes prescribed for prostate problems or high blood pressure. If GIOXIL-36 is taken with certain alpha blockers, your blood pressure

could suddenly drop. You could get dizzy or faint.

- other medicines to treat high blood pressure (hypertension)
- medicines called HIV protease inhibitors, such as ritonavir (Norvir®, Kaletra®)
- ketoconazole (Nizoral®)
- itraconazole (Sporanox®)
- erythromycin
- other medicines or treatments for ED.
- GIOXIL-36 is also marketed as ADCIRCA for the treatment of pulmonary arterial hypertension. Do not take both GIOXIL-36 and ADCIRCA. Do not take sildenafil citrate (Revatio™) with GIOXIL-36.

How Should I Take GIOXIL-36?

- Take GIOXIL-36 exactly as your healthcare provider prescribes it. Your healthcare provider will prescribe the dose that is right for you.
- Some men can only take a low dose of GIOXIL-36 or may have to take it less often, because of medical conditions or medicines they take.
- Do not change your dose or the way you take GIOXIL-36 without talking to your healthcare provider. Your healthcare provider may lower or raise your dose, depending on how your body reacts to GIOXIL-36 and your health condition.
- GIOXIL-36 may be taken with or without meals.
- If you take too much GIOXIL-36, call your healthcare provider or emergency room right away.

There are two ways to take GIOXIL-36:

GIOXIL-36 for use as needed:

- **Do not take GIOXIL-36 more than one time each day.**
- Take one GIOXIL-36 tablet before you expect to have sexual activity. You may be able to have sexual activity at 30 minutes after taking GIOXIL-36 and up to 36 hours after taking it.

You and your healthcare provider should consider this in deciding when you should take GIOXIL-36 before sexual activity. Some form of sexual stimulation is needed for an erection to happen with GIOXIL-36.

- Your healthcare provider may change your dose of GIOXIL-36 depending on how you respond to the medicine, and on your health condition.

OR GIOXIL- daily use:

- **Do not take GIOXIL-36 more than one time each day.**
- Take one GIOXIL-36 tablet every day at about the same time of day. You may attempt sexual activity at any time between doses.
- If you miss a dose, you may take it when you remember but do not take more than one dose per day.
- Some form of sexual stimulation is needed for an erection to happen with GIOXIL-36.
- Your healthcare provider may change your dose of GIOXIL-36 depending on how you respond to the medicine, and on your health condition.

What Should I Avoid While Taking GIOXIL-36?

- Do not use other ED medicines or ED treatments while taking GIOXIL-36.
- Do not drink too much alcohol when taking GIOXIL-36 (for example, 5 glasses of wine or 5 shots of whiskey). Drinking too much alcohol can increase your chances of getting a headache or getting dizzy, increasing your heart rate, or lowering your blood pressure.

What Are The Possible Side Effects Of GIOXIL-36?

See **“What Is The Most Important Information I Should Know About GIOXIL-36?”**

The most common side effects with GIOXIL-36 are: headache, indigestion, back pain, muscle aches, flushing, and stuffy or runny nose. These side effects usually go away after a few hours.

Men who get back pain and muscle aches usually get it 12 to 24 hours after taking GIOXIL-36. Back pain and muscle aches usually go away within 2 days.

Call your healthcare provider if you get any side effect that bothers you or one that does not go away.

Uncommon side effects include:

An erection that won't go away (priapism). If you get an erection that lasts more than 4 hours, get medical help right away. Priapism must be treated as soon as possible or lasting damage can happen to your penis, including the inability to have erections.

Color vision changes, such as seeing a blue tinge (shade) to objects or having difficulty telling the difference between the colors blue and green.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including GIOXIL-36) reported a sudden decrease or loss of vision in one or both eyes.

It is not possible to determine whether these events are related directly to these medicines, to other factors such as high blood pressure or diabetes, or to a combination of these. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including GIOXIL-36, and call a healthcare provider right away.

Sudden loss or decrease in hearing, sometimes with ringing in the ears and dizziness, has been rarely reported in people taking PDE5 inhibitors, including GIOXIL-36. It is not possible to determine whether these events are related directly to the PDE5 inhibitors, to other diseases or medications, to other factors, or to a combination of factors.

If you experience these symptoms, stop taking GIOXIL-36 and contact a healthcare provider right away.

These are not all the possible side effects of GIOXIL-36. For more information, ask your healthcare provider or pharmacist.

How Should I Store GIOXIL-36?

Store GIOXIL-36 at room temperature between 59° and 86°F (15° and 30°C).

Keep GIOXIL-36 and all medicines out of the reach of children.

General Information About GIOXIL-36:

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use GIOXIL-36 for a condition for which it was not prescribed. Do not give GIOXIL-36 to other people, even if they have the same symptoms that you have. It may harm them.

This is a summary of the most important information about GIOXIL-36. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about GIOXIL-36 that is written for health providers. For more information you can also visit www.GIOXIL-36.com, or call 1-877-GIOXIL-361 (1-877-242-5471).

What Are The Ingredients In GIOXIL-36?

Active Ingredient: Lepidium meyenii (Maca root) 200mg, Ptychopetalum olacoides - Root (Muirapuama) 20mg and Hydroxyhomosildenafil 20mg

Rx only

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FIRSTMED PHARMA, INC

Dothan, AL 36301, USA

www.GIOXIL-36.com

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