

MEDICATION GUIDE
PASATRU™ (PA-SAH-TROO)
(garetoismab-grts)
injection, for intravenous use

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

PASATRU can cause serious side effects, including:

- **Harm to your unborn baby including serious birth defects if taken during pregnancy. Females who are pregnant must not take PASATRU.**
 - **Females who can become pregnant:**
 - Your healthcare provider will ask you to take a pregnancy test to verify that you are not pregnant before starting treatment with PASATRU.
 - Use effective birth control (contraception) during treatment with PASATRU and for 6 months after the last dose of PASATRU. Talk to your healthcare provider about birth control methods that may be right for you.
 - If you become pregnant or think you may be pregnant during treatment with PASATRU, **stop taking PASATRU immediately and call your healthcare provider right away.**
- **Infections of the skin and tissue under the skin** requiring treatment or hospitalization, such as infected lumps (abscesses) and bacterial skin infections (cellulitis), may happen while you are taking PASATRU. Call your healthcare provider right away if you have signs or symptoms of skin infection, such as:
 - redness
 - skin feels warm to the touch
 - swelling
 - pain or tenderness
 - fever
 - feeling generally unwell
- **Nosebleeds (epistaxis)** including serious nosebleeds that require medical care, can happen while taking PASATRU. **Tell your healthcare provider right away if you have a nosebleed that:**
 - is severe or heavy
 - does not stop with basic first-aid measures, such as pinching your nose with continuous firm pressure
 - lasts more than 20 minutes

See "**What are the possible side effects of PASATRU?**" for more information about side effects.

What is PASATRU?

PASATRU is a prescription medicine used to reduce the formation of new abnormal bone growth outside of the skeleton (heterotopic ossification) and flare-ups in adults with fibrodysplasia ossificans progressiva (FOP). It is not known if PASATRU is safe and effective in children.

Who should not receive PASATRU?

Do not receive PASATRU if you:

- are pregnant. (See "**What is the most important information I should know about PASATRU?**")

Before you receive PASATRU, tell your healthcare provider about all your medical conditions, including if you:

- are breastfeeding. It is not known whether PASATRU passes into your breast milk. Breastfeeding is not recommended during treatment with PASATRU and for 6 months after the last dose of PASATRU. Talk to your healthcare provider about the best way to feed your baby during this time.
- are concerned about male fertility. PASATRU may affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive PASATRU?

- Your healthcare provider will give you PASATRU through a needle placed into your vein (intravenous infusion) over 60 minutes.
- PASATRU should be given 1 time every 4 weeks.
- If you miss any infusion appointments, call your healthcare provider as soon as possible to reschedule. After you receive your missed dose, your next infusion will be scheduled every 4 weeks from the date of that dose.

What are the possible side effects of PASATRU?

PASATRU may cause serious side effects, including:

- See "**What is the most important information I should know about PASATRU?**"

The most common side effects of PASATRU include:

- infected lumps (abscess)
- hair loss of eyebrows or lashes (madarosis)
- acne
- mouth sores (oral ulcers)
- increased hair growth
- nosebleeds (epistaxis)

These are not all of the possible side effects of PASATRU.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of PASATRU.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider or pharmacist for information about PASATRU that is written for health professionals.

What are the ingredients in PASATRU?**Active ingredient:** garetosmab-grts**Inactive ingredients:** arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 20, sucrose, and Water for Injection, USP.

Manufactured by: Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591 U.S. License No. 1760

For more information about PASATRU, go to www.PASATRU.com or call 1-877-372-7287.

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