

For families & people living with PKU

Your step-by-step guide to SEPHIENCE dosing


Sephience™
sepiapterin
250 mg | 1000 mg Oral Powder

What is SEPHIENCE?

SEPHIENCE™ (sepiapterin) is a prescription medicine used to lower blood levels of phenylalanine (Phe) in adults and children 1 month of age and older with a certain type of Phenylketonuria (PKU). SEPHIENCE is used along with a Phe-restricted diet. It is not known if SEPHIENCE is safe and effective in children younger than 1 month of age.

Dosing that fits into your day, every day



Once a day, with food. It is best to take SEPHIENCE at the same time each day



Dosing is based on age and weight



Available in 250 mg and 1000 mg packets for flexible dosing



To be used in combination with a Phe-restricted diet

Always ask your healthcare provider or pharmacist if you have any questions on how to take SEPHIENCE.

IMPORTANT SAFETY INFORMATION

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

SEPHIENCE may cause serious side effects, including:

- **increased bleeding problems.** SEPHIENCE may increase your risk of bleeding. Tell your healthcare provider if you develop any symptoms of bleeding including:
 - bruising or red or purple skin marks
 - menstrual bleeding that is heavier than normal
 - bleeding longer than usual or that does not stop
- **low blood Phe (hypophenylalaninemia).** Low blood Phe levels are common during treatment with SEPHIENCE and can be severe.

The most common side effects of SEPHIENCE include: diarrhea, headache, stomach (abdominal) pain, yellow or orange stool (feces), and throat pain.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of SEPHIENCE. Call your healthcare provider for medical advice about side effects.

Please see additional Important Safety Information throughout and the [Full Prescribing Information](#).



Norah,
Living with PKU

Once-daily dosing

Taking SEPHIENCE™

- Take SEPHIENCE once a day, with food
 - Additional food intake is required after dosing
- It's best to take SEPHIENCE at the same time each day
- Your doctor will tell you the right dose based on your (or your loved one's) body weight and age

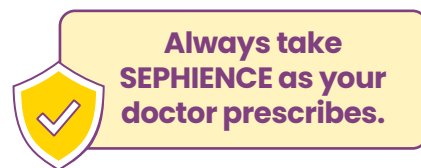
Mixing SEPHIENCE

- Comes in **250 mg** and **1000 mg** powder packets
- Mix with water, apple juice, or soft food (only for doses ≥ 1000 mg) like applesauce or strawberry jam
- May cause staining when in contact with certain surfaces. To minimize this risk, use as directed

Daily personal dose tracker

Your doctor will determine the dose of SEPHIENCE that's right for you. This dose tracker is **for informational use only and does not replace medical advice**. Always follow your doctor's instructions.

For additional dosing guidance, visit the [dose calculator on the SEPHIENCE website](#).



If the daily dose is:
<1000 mg

Daily dose mg	Number of packets		OR		Mix in		Prescribed volume mL to be administered
		250 mg			1000 mg		

OR

If the daily dose is:
 ≥ 1000 mg

Daily dose mg	Number of packets		AND/OR		Mix in		Administer the full volume
		250 mg			1000 mg		

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking or giving SEPHIENCE, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if SEPHIENCE will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SEPHIENCE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take SEPHIENCE.

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SEPHIENCE and other medicines may affect each other causing side effects. SEPHIENCE may affect the way other medicines work, and other medicines may affect how SEPHIENCE works. Especially tell your healthcare provider if you take:

- a medicine that contains levodopa
- another medicine also used to lower Phe
- an antifolate medicine
- medicines used to treat erectile dysfunction (phosphodiesterase 5 inhibitors or PDE5)

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

Please see additional Important Safety Information throughout and the [Full Prescribing Information](#).



Follow these steps below to take SEPHIENCE



1 Prepare

Mix the correct number of packets with water, apple juice, or soft food (only for doses ≥ 1000 mg), such as applesauce or strawberry jam.



2 Mix until combined

- Stir liquids for at least 30 seconds
- Stir soft foods for at least 60 seconds

Note: oral powder is not expected to dissolve completely. This is normal.



3 Use as directed

- Drink or swallow the full amount
- For doses < 1000 mg: Use an oral syringe to draw up the prescribed dose and administer



4 Rinse & finish

- Rinse the cup or syringe with water or juice
- Swallow the rinse until clean to make sure you get the full dose



5 If you need to store it

- If not taken right away, cover and store the mix:
 - In the refrigerator (36°F to 46°F / 2°C to 8°C) for up to 24 hours
 - At room temperature (68°F to 77°F / 20°C to 25°C) for up to 6 hours
- Stir again before using (see step 2)

Refer to page 18 [here](#) for the Instructions for Use.



Seth,
Living with PKU

IMPORTANT SAFETY INFORMATION (cont'd)

How should I take or give SEPHIENCE?

- Take or give SEPHIENCE exactly as your healthcare provider tells you. Your healthcare provider will tell you how much SEPHIENCE to take or give.
- Your healthcare provider may change your or your child's dose of SEPHIENCE depending on your weight and age.
- Take or give SEPHIENCE 1 time each day with food. You must take or give more food after the SEPHIENCE dose.
- SEPHIENCE comes as a packet containing oral powder.
 - For SEPHIENCE doses **less than** 1,000 mg: mix SEPHIENCE oral powder with water or apple juice before giving or taking.
 - For SEPHIENCE doses 1,000 mg or **greater**: SEPHIENCE oral powder can be mixed with water, apple juice, strawberry jam, or applesauce before taking or giving.
 - **See the detailed Instructions for Use that comes with SEPHIENCE for information about the correct way to prepare, take, or give a dose of SEPHIENCE oral powder.**

Please see additional Important Safety Information throughout and the [Full Prescribing Information](#).





Living with PKU, on your terms

Managing PKU is a lifelong journey—but it doesn't have to be limiting. SEPHIENCE can help control Phe levels, allowing you to focus on what's important to you.

Learn more at
SEPHIENCE.com



Need support or have questions? We're here for you. Contact PTC Cares™



Call: 1-844-4PTC-CARES (1-844-478-2227)
Monday to Friday, 8am to 6pm (EST)



Website: www.ptccares.com

IMPORTANT SAFETY INFORMATION (cont'd)

How should I take or give SEPHIENCE? (cont'd)

- If you or your child miss a dose of SEPHIENCE, take or give it as soon as possible. Do not take 2 doses in a day. Continue with your normal dosing schedule the following day.
- During treatment with SEPHIENCE, you or your child will have regular check-ups with your healthcare provider.
- Your healthcare provider will do blood tests before and during your treatment with SEPHIENCE to check your blood Phe levels.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with SEPHIENCE if you have certain side effects.
- Your healthcare provider may change your diet during treatment. Follow your healthcare provider's instructions and do not make any changes to your diet without first talking to your healthcare provider.

To report an adverse event, please call 1-866-562-4620 or email at usmedinfo@ptcbio.com.

You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

Please see [Full Prescribing Information](#).



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