

Pegvaliase – Factsheet

April 2022



What is Pegvaliase?

Product Name: Palynziq

[Pegvaliase \(Palynziq\)](#) was listed on the Australian Register of Therapeutic Goods (SRTG) on the 6 July 2021 by the Therapeutic Goods Administration (TGA) for the following therapeutic use:

Palynziq is indicated for the treatment of patients with phenylketonuria (PKU) aged 16 years and older who have inadequate blood phenylalanine control despite prior management with available treatment options.

Treatment with Pegvaliase should be directed by physicians experienced in the management of phenylketonuria and in the context of a multidisciplinary team, including dietitians.

What is this medicine and how does it work?

Pegvaliase acts in blood to reduce levels of circulating phenylalanine.

Pegvaliase acts independently of tetrahydrobiopterin, so all PKU patients requiring treatment are potentially treatable with pegvaliase.

What are the active ingredients?

Active ingredient: Pegvaliase

Pegvaliase (Palynziq) is currently available in solution form for subcutaneous injection.

Palynziq solution for injection is a clear to slightly opalescent, colourless to pale yellow solution in a pre-filled syringe. The pre-filled syringe includes an automatic needle guard.

Who is eligible for Pegvaliase?

Patients with phenylketonuria (PKU) aged 16 years and older who have inadequate blood phenylalanine control despite prior management with available treatment options.

Pegvaliase is not yet available on the Pharmaceutical Benefit Scheme (PBS)

Pregnancy

The use of any medicine during pregnancy requires careful consideration of both risks and benefits by the treating health professional.

Additional Resources & Information

MDDA's position is that **all Australians living with PKU should have access to all treatments that have been approved as safe and effective by the Therapeutic Goods Administration (TGA)**. This means that Australian clinicians should be given the choice of selecting the treatment that best meets the needs of each individual patient and will lead to optimal treatment outcomes – without any limitations or restrictions.

If you would like to be kept informed about the latest updates and next steps as they become known, please ensure your contact details are up to date with MDDA and follow our website and Facebook.

<https://www.tga.gov.au/auspar/auspar-pegvaliase>

<https://www.tga.gov.au/apm-summary/palynziq>

https://www.healthdirect.gov.au/medicines/brand/amt_1596261000168103/palynziq

Consumer Medicine Information summary

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-CMI-01919-1&d=20220406172310101>