



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Byannli<sup>1</sup> (*paliperidone*)

An overview of Byannli and why it is authorised in the EU

### What is Byannli and what is it used for?

Byannli is an antipsychotic medicine used for the maintenance treatment of schizophrenia in adults whose disease has already been stabilised on treatment with injections of paliperidone given every month or every three months.

Byannli contains the active substance paliperidone.

This medicine is similar to Xeplion and Trevicta, which are already authorised in the EU, but are available in different strengths. Scientific data from Xeplion was used during the initial authorisation of Byannli ('informed consent').

### How is Byannli used?

Byannli is available as a prolonged-release suspension for injection in pre-filled syringes (700 and 1,000 mg). 'Prolonged-release' means that the active substance is released slowly over a few weeks after being injected.

Byannli is injected once every 6 months in the gluteal muscle (buttocks); the dose depends on the previous monthly or three-monthly dose.

For more information about using Byannli, see the package leaflet or contact your doctor or pharmacist.

### How does Byannli work?

The active substance in Byannli, paliperidone, is an active breakdown product (metabolite) of risperidone, another antipsychotic medicine that has been used in the treatment of schizophrenia since the 1990s. In the brain, it attaches to several different receptors on nerve cells. This disrupts signals transmitted between brain cells by 'neurotransmitters', chemicals that allow nerve cells to communicate with each other. Paliperidone acts mainly by blocking receptors for the neurotransmitters dopamine and 5-hydroxytryptamine (also called serotonin), which are involved in schizophrenia. By

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<sup>1</sup> Previously known as Paliperidone Janssen-Cilag International.



blocking these receptors, paliperidone helps to normalise the activity of the brain and reduce symptoms of the disease.

Paliperidone has been authorised in the European Union as Invega since 2007 as an oral treatment for schizophrenia. In Byannli, paliperidone has been attached to a fatty acid that allows it to be released slowly after being injected. This allows for the injection to have a long duration of action.

### **What benefits of Byannli have been shown in studies?**

Because paliperidone has already been authorised in the EU, the company used some of the data from authorised medicines to support the use of Byannli.

In a main study involving 702 schizophrenia patients stabilised on monthly or three-monthly paliperidone injections, Byannli (given six-monthly) was as effective in preventing relapses as another paliperidone injections every 3 months. In this study, 92.5% of the patients receiving six-monthly Byannli treatment were relapse-free during a 12-month period. By comparison, 95.1% of the patients receiving three-monthly paliperidone palmitate injectable treatment were relapse-free during the same 12-month period.

### **What are the risks associated with Byannli?**

The most frequently reported side effects (which may affect more than 1 in 20 people) are headache, upper respiratory tract infection (infections of the throat and nose), reactions at the site of injection, parkinsonism (neurological symptoms including tremor and impaired muscular control) and increased weight.

For the full list of side effects and restrictions, see the package leaflet.

### **Why is Byannli authorised in the EU?**

A main study showed that Byannli given every six months is as effective as paliperidone injections given every three months, with no serious side effects reported. The longer dosing interval might also offer benefits to individuals with limited access to healthcare.

The European Medicines Agency, therefore, decided that Byannli's benefits are greater than its risks and it can be authorised for use in the EU.

### **What measures are being taken to ensure the safe and effective use of Byannli?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Byannli have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Byannli are continuously monitored. Side effects reported with Byannli are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Byannli**

Paliperidone Janssen-Cilag International received a marketing authorisation valid throughout the EU on 18 June 2020.

The name of the medicine was changed to Byannli on 22 November 2021.

Further information on Byanli can be found on the Agency's website:  
[ema.europa.eu/medicines/human/EPAR/byanli](https://ema.europa.eu/medicines/human/EPAR/byanli).

This overview was last updated in 11-2021.