

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using JOENJA?

JOENJA contains the active ingredient leniolisib. JOENJA is used to treat activated phosphoinositide 3-kinase delta syndrome (APDS) in adults and adolescents 12 years of age and older.

For more information, see Section [1. Why am I using JOENJA?](#) in the full CMI.

### 2. What should I know before I use JOENJA?

Do not use if you have ever had an allergic reaction to JOENJA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** Your doctor will do a test to see if you are pregnant before beginning treatment with Joenja.

For more information, see Section [2. What should I know before I use JOENJA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with JOENJA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use JOENJA?

- The usual dose is one 70 mg tablet twice daily, taken every 12 hours at about the same time each morning and evening. You can take JOENJA with or without food.

More instructions can be found in Section [4. How do I use JOENJA?](#) in the full CMI.

### 5. What should I know while using JOENJA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you become pregnant or plan to become pregnant, breastfeed or plan to breastfeed. Call your doctor right away if you become pregnant while taking this medicine.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using JOENJA.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly or change the dosage without consulting your doctor.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store JOENJA below 30°C.</li><li>• Do not refrigerate JOENJA.</li></ul>

For more information, see Section [5. What should I know while using JOENJA?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects may include infection of the airways, including cough, sore throat, and/or wheezing, and headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# JOENJA<sup>®</sup> (jo en' jah)

Active ingredient(s): [*leniolisib*]

## Consumer Medicine Information (CMI)

This leaflet provides important information about using JOENJA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using JOENJA.**

Where to find information in this leaflet:

- [1. Why am I using JOENJA?](#)
- [2. What should I know before I use JOENJA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use JOENJA?](#)
- [5. What should I know while using JOENJA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using JOENJA?

JOENJA contains the active ingredient leniolisib. JOENJA belongs to a group of medicines called immunostimulants. These are enzymes required for transmission of signals in the cells of the body. Leniolisib regulates activated phosphoinositide 3-kinases and helps to treat symptoms of immunodeficiency.

JOENJA is used to treat activated phosphoinositide 3-kinase delta syndrome (APDS) in adults and adolescents 12 years of age and older.

### 2. What should I know before I use JOENJA?

#### Warnings

**Do not use JOENJA if:**

- you are allergic to leniolisib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- take any medicines for any other condition
- have liver problems
- are planning to receive a vaccine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Although not reported with JOENJA, serious and sometimes fatal infections, skin reactions, breathing problems, diarrhoea, low white blood cell counts, and liver problems have occurred in patients receiving other PI3K delta inhibitors for the treatment of certain cancers. Tell your doctor right away if you become ill while taking JOENJA.

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. If you become pregnant while you are being treated with JOENJA tell your doctor immediately.

Your doctor will do a test to see if you are pregnant before beginning treatment with Joenja.

You should not be given JOENJA if you are pregnant. This is because it is possible that JOENJA can harm your unborn baby.

If you could become pregnant, use adequate contraception while using JOENJA and for at least 1 week after the last JOENJA dose. Talk to your doctor about your contraception options.

Do not breast-feed while receiving JOENJA. This is because it is not known if this medicine can pass into breast milk and harm your baby.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

JOENJA has been reported to interfere with the way some other drugs act; also, certain drugs may interfere with the way JOENJA acts. Therefore, it is important to let your doctor and pharmacist know any other drugs that you are taking so that they can decide if there is any interference between them and JOENJA.

Medicines that neutralise or bind stomach acid (locally acting antacids) may affect how JOENJA works. Take these medicines 2 hours before or 2 hours after taking JOENJA.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect JOENJA.**

### 4. How do I use JOENJA?

#### How much to take

- The usual dose is one 70 mg tablet twice daily.

- If vomiting occurs within 1 hour after taking the tablet, take another tablet right away. If you vomit more than 1 hour after taking the tablet, wait and take the next dose at your usual scheduled time.
- You can take JOENJA with or without food.

### When to take JOENJA

- Take JOENJA every 12 hours at about the same time each morning and evening.
- Always take JOENJA every day exactly as your healthcare professional has told you to.

### If you forget to take JOENJA

JOENJA should be used regularly at the same time each day. If you miss a dose by more than 6 hours, do not take another tablet. Wait and take the next dose at your usual scheduled time.

### If you take too much JOENJA

If you think that you have taken too much JOENJA, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using JOENJA?

### Things you should do

**Tell your doctor if you become pregnant or plan to become pregnant, breastfeed or plan to breastfeed. Call your doctor right away if you become pregnant while taking this medicine.**

Remind any doctor, dentist or pharmacist you visit that you are using JOENJA.

### Things you should not do

- Do not stop using this medicine suddenly or change the dosage without consulting your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you.

### Looking after your medicine

- Store JOENJA below 30°C.
- Do not refrigerate JOENJA.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, contact your doctor or pharmacist if you have any further questions about side effects.

### Side effects

Less serious side effects	What to do
<p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>• fast heart rate</li> </ul> <p><b>Stomach related:</b></p> <ul style="list-style-type: none"> <li>• diarrhoea</li> <li>• vomiting</li> </ul> <p><b>Body as a whole:</b></p> <ul style="list-style-type: none"> <li>• tiredness</li> <li>• fever</li> </ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>• sneezing, itching, runny, and blocked nose</li> <li>• infection of the airways, including cough, sore throat, and/or wheezing</li> <li>• infection of the sinuses (spaces inside your face usually filled with air), causing feelings of pressure and pain in your face and a stuffy nose.</li> <li>• inflammation of the outer ear</li> <li>• infection of the lungs, including chest pain, cough, fever, and shortness of breath</li> </ul> <p><b>Muscle related:</b></p> <ul style="list-style-type: none"> <li>• back pain</li> <li>• neck pain</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>• headache</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>• skin inflammation with rash</li> <li>• hair loss</li> </ul> <p><b>Weight related:</b></p> <ul style="list-style-type: none"> <li>• weight gain</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Blood related:</b> <ul style="list-style-type: none"> <li>infections, fever, or painful swallowing – these may be signs of reduced number of white blood cells called neutrophils</li> </ul>	
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	Macrogol 4000
<b>Potential allergens</b>	This medicine contains lactose monohydrate.

**Do not take this medicine if you are allergic to any of these ingredients.**

### Serious side effects

Serious side effects	What to do
<b>Signs of an allergic reaction, such as:</b> <ul style="list-style-type: none"> <li>chest tightness,</li> <li>shortness of breath, wheezing or difficulty breathing,</li> <li>swelling of the face lips, tongue, or other parts of the body,</li> <li>hives itching or skin rash.</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What JOENJA contains

<b>Active ingredient (main ingredient)</b>	leniolisib (as phosphate) 70 mg
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate microcrystalline cellulose hypromellose sodium starch glycollate Type A magnesium stearate silicon dioxide titanium dioxide iron oxide yellow iron oxide red purified talc

### What JOENJA looks like

JOENJA film-coated tablets are yellow, oval shaped, biconvex, with a bevelled edge, debossed with "70" on one side and "LNB" on the other side.

Each pack contains 1 bottle with 60 tablets. (Aust R 416199).

### Who distributes JOENJA

Pharming Australia Pty Ltd  
Level 29, 66 Goulburn Street  
Sydney NSW 2000

This leaflet was prepared in July 2025.