

Package leaflet: Information for the patient

Joenja 70 mg film-coated tablets leniolisib

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Joenja is and what it is used for
2. What you need to know before you take Joenja
3. How to take Joenja
4. Possible side effects
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6. Contents of the pack and other information

1. What Joenja is and what it is used for

Joenja contains the active substance leniolisib, which belongs to a group of medicines called phosphoinositide 3-kinases inhibitors. These are enzymes required for transmission of signals in the cells. 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 from 12 years who weigh 45 kg or more.

Patients with this syndrome can have serious problems with their immune system and suffer from the effects of their immunodeficiency.

2. What you need to know before you take Joenja

Do not take Joenja

- if you are allergic to leniolisib or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Harm to your unborn baby

Treatment with Joenja during pregnancy can cause harm to your unborn baby. Your doctor may have you take a pregnancy test before starting treatment with Joenja. Women who can become pregnant should use highly effective birth control throughout the duration of treatment with Joenja and for 1 week after the last dose of Joenja. Talk to your doctor about birth control methods that may be right for you.

Liver problems

Talk to your doctor or pharmacist before taking Joenja if you have moderately or severely reduced liver function. Joenja is not recommended in these patients.

Vaccinations

Vaccines that contain live or live but weakened organisms, known as live, attenuated vaccines (like measles, mumps, and rubella vaccines) may be less effective if administered during Joenja treatment.

Children and adolescents

Do not give Joenja to children under 12 years because it has not been studied in this age group.

Other medicines and Joenja

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Certain medicines taken with Joenja may change how it works or Joenja may stop them from working properly.

Tell your doctor or pharmacist if you are taking any of the following medicines as they may change how Joenja works:

- avasimibe – used to treat build-up of cholesterol plaque in the arteries
- bosentan – used to treat pulmonary arterial hypertension (PAH)
- carbamazepine, phenobarbital, phenytoin – used to treat seizures (epilepsy)
- cobicistat, efavirenz, elvitegravir, etravirine, indinavir, lopinavir, nevirapine, ritonavir, saquinavir, tipranavir – used to treat human immunodeficiency virus (HIV) infection
- danoprevir, dasabuvir, ombitasvir, paritaprevir – used to treat hepatitis C (HCV)
- diltiazem, verapamil – used to treat high blood pressure (hypertension)
- itraconazole, ketoconazole, posaconazole, voriconazole – used to treat fungal infections
- mitotane – cancer therapy
- modafinil – used to treat excessive daytime sleepiness (narcolepsy)
- clarithromycin, erythromycin, nafcillin, rifabutin, rifampin, telithromycin, troleandomycin – used to treat bacterial infections
- St. John’s Wort (*Hypericum perforatum*) – a herbal medicine for depression and sleep problems

Also, tell your doctor or pharmacist if you are taking any of the following medicines, which may be affected when used with Joenja:

- alosetron – used to treat irritable bowel syndrome (IBS) in women
- duloxetine – used to treat depression
- letermovir – used to prevent cytomegalovirus (CMV) infection
- melatonin, ramelteon, tasimelteon – used to treat insomnia
- rosuvastatin, pitavastatin – used to lower cholesterol
- theophylline – used to treat asthma
- tizanidine – used to relax muscles

Joenja with food and drink

Do not eat grapefruit or drink grapefruit juice while taking Joenja. Grapefruit may increase the amount of leniolisib in your body.

Pregnancy and breast-feeding

• Pregnancy

- Joenja is not recommended during pregnancy. There is no information about the safety of this medicine in pregnant women. Your doctor will test to see if you are pregnant before beginning treatment with Joenja.
- For women who could become pregnant, Joenja is not recommended if not using highly effective contraception during treatment. Continue contraception for at least 1 week after the last dose of Joenja. Ask your doctor about suitable methods of contraception.
- If you think you may be pregnant after starting treatment with Joenja, tell your doctor immediately.

• Breast-feeding

- Do not breast-feed while taking Joenja. Tell your doctor before you take this medicine if you are breast-feeding or are planning to breast-feed. It is not known if Joenja can pass into breast milk or if this would affect the baby.

Driving and using machines

This medicine has no or negligible influence on your ability to drive or use machines.

Joenja contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3. How to take Joenja

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is

1 tablet twice daily, approximately 12 hours apart in adults and adolescents from 12 years weighing 45 kg or more.

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, take the next dose at your usual time.

This medicine can be taken with or without food. The tablets should be swallowed whole. The tablets should not be split, crushed, or chewed.

If you take more Joenja than you should

Contact your doctor or nearest emergency department immediately for advice if this occurs. Keep the bottle and this leaflet with you so that you can easily describe what you have taken.

If you forget to take Joenja

If you miss a dose by more than 6 hours, wait and take the next dose at your usual time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Joenja

Do not stop taking this medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects may occur with the following frequencies:

Very common: may affect more than 1 in 10 people

- headache
- swollen/inflamed sinuses
- skin inflammation with rash
- faster heartbeat
- diarrhoea
- tiredness
- fever
- back pain
- neck pain
- hair loss

Decrease in white blood cell counts

Joenja may lower the number of a type of white blood cells called neutrophils.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Joenja

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Joenja contains

- The active substance is leniolisib. Each film-coated tablet contains leniolisib phosphate equivalent to 70 mg leniolisib.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (Type A), hypromellose, magnesium stearate, colloidal silicon dioxide. The coating ingredients are hypromellose, titanium dioxide, talc, macrogol/polyethylene glycol, iron oxide yellow, and iron oxide red. See section 2 “Joenja contains lactose and sodium”.

What Joenja looks like and contents of the pack

Joenja 70 mg film-coated tablets are yellow, oval-shaped, bevelled edge film-coated tablets debossed with “70” on one side and “LNB” on the other side.

Each pack contains 1 bottle with 60 tablets.

Marketing Authorisation Holder and Manufacturer

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