

Jascayd® 9 mg film-coated tablets

Jascayd® 18 mg film-coated tablets

nerandomilast



▼ 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Jascayd is and what it is used for

What Jascayd is

Jascayd contains the active substance nerandomilast.

It is a medicine called a phosphodiesterase 4B inhibitor, which helps to regulate the activity of your immune system and to reduce tissue scarring.

What Jascayd is used for

Jascayd is used:

- to treat adults with a lung disease called Idiopathic Pulmonary Fibrosis (IPF).
- to treat adults with a lung disease called Progressive Pulmonary fibrosis (PPF).

IPF and PPF are conditions in which the tissue in your lungs becomes thickened, stiff and scarred over time. As a result, scarring reduces the ability to transfer oxygen from the lungs into the bloodstream and it becomes difficult to breathe deeply. Jascayd helps to reduce further scarring and stiffening of the lungs and helps you to breathe better.

2. What you need to know before you take Jascayd

Do not take Jascayd

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

Children

Do not give this medicine to children. It is not known if this medicine is safe and effective in children.

Other medicines and Jascayd

Jascayd may affect the way other medicines work, and other medicines may affect how Jascayd works.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

This is especially important if you are taking pirfenidone (another medicine to treat IPF), as it can reduce how well Jascayd works.

Tell your doctor if you take any of the medicines listed below. Your doctor may reduce your dose of Jascayd if you take any of these.

- Clarithromycin: an antibiotic medicine to treat bacterial infections
- Itraconazole: a medicine to treat fungal infections
- Ritonavir: a medicine to treat HIV infections

Additionally, tell your doctor or pharmacist before taking Jascayd if you are taking any of the following medicines as it is expected that they may reduce how well Jascayd works:

- Carbamazepine: a medicine to treat epilepsy and certain nerve pain
- St. John's wort: a herbal medicine used to help with mild depression, symptoms of menopause, and certain mood-related conditions such as anxiety
- Rifampicin: an antibiotic medicine to treat tuberculosis and other bacterial infections
- Phenytoin: a medicine to treat epilepsy
- Bosentan: a medicine to treat pulmonary arterial hypertension
- Metamizole: a medicine to relieve pain and reduce fever

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine may cause loss of your pregnancy (miscarriage). You should use effective contraception during treatment with Jascayd. If you become pregnant while being treated with this medicine, tell your doctor straight away. You and your doctor will decide if the benefit of having the medicine is greater than the risk to your baby.

It is not known if this medicine passes into your breastmilk. Do not breastfeed during treatment with Jascayd.

Driving and using machines

This medicine is not expected to affect your ability to drive and use machines.

Jascayd contains lactose

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

Jascayd contains sodium

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

3. How to take Jascayd

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

Your doctor will tell you how much Jascayd to take and when to take it.

The recommended dose is 1 tablet of Jascayd 18 mg twice daily. Take the tablets approximately 12 hours apart.

Your doctor may decide to reduce your dose of Jascayd to 9 mg twice daily depending on:

- How well you tolerate Jascayd or
- Any other medicines you are taking.

Taking this medicine

- Swallow the tablets whole with water.
- You can take the tablet with or without food.

If you cannot swallow Jascayd tablets whole:

- Place about 100 mL of non-carbonated, room temperature water in a glass. Do not use any other liquids.
- Drop the tablet in water without crushing it.
- Stir regularly for approximately 15 to 20 minutes until the tablet is in very small pieces (the tablet will not completely dissolve).
- Drink the Jascayd and water mixture within 2 hours of mixing.
- If you do not drink the mixture right away, stir the mixture again before drinking.
- Rinse the glass with about 100 mL of water and drink it. This ensures you have taken the full dose.

If you take more Jascayd than you should

Contact your doctor or pharmacist immediately.

If you forget to take Jascayd

If you forget a dose, take your next dose at your regular time. **Do not** take the missed dose. **Do not** take more than 2 tablets of 18 mg Jascayd in 1 day.

If you stop taking Jascayd

You should continue taking Jascayd until your doctor tells you to stop. Do not stop taking Jascayd without talking to your doctor first.

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.

Talk to your doctor if you get any side effects.

Very common side effects (may affect more than 1 in 10 people):

- Diarrhoea
- Weight loss

Common side effects (may affect up to 1 in 10 people):

- Nausea
- Decreased appetite
- Back pain

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Jascayd

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 blister or label and on the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater. 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 Jascayd contains

Jascayd 9 mg tablets:

- The active substance is nerandomilast. Each tablet contains 9 mg nerandomilast.
- The other ingredients are:
 - Lactose monohydrate
 - Microcrystalline cellulose
 - Hydroxypropylcellulose
 - Croscarmellose sodium
 - Magnesium stearate
 - Hypromellose 2910
 - Talc
 - Mannitol
 - Macrogol 8000
 - Iron oxide yellow (E172)

Jascayd 18 mg tablets

- The active substance is nerandomilast. Each tablet contains 18 mg nerandomilast.
- The other ingredients are:
 - Lactose monohydrate
 - Microcrystalline cellulose
 - Hydroxypropylcellulose
 - Croscarmellose sodium
 - Magnesium stearate
 - Hypromellose 2910
 - Talc

- Mannitol
- Macrogol 8000
- Iron oxide red (E172)
- Iron oxide black (E172)

What Jascayd looks like and contents of the pack

Jascayd 9 mg film-coated tablets are light yellow, oval and biconvex. They have “F9” on one side and the Boehringer Ingelheim logo on the other side. The tablets are 9.5 mm long and 4.6 mm wide.

Jascayd 18 mg film-coated tablets are light red, oval and biconvex. They have “F18” on one side and the Boehringer Ingelheim logo on the other side. The tablets are 12 mm long and 5.9 mm wide.

- Jascayd tablets are available in:
- PVC/aluminium perforated unit dose blisters.
The pack sizes are 10 x 1, 30 x 1 or 60 x 1 film-coated tablets.
 - HDPE bottle with a child-resistant closure.
The pack sizes are 60 or 180 film-coated tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

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Manufacturer

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